IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

CENTOCOR, ET AL	*	Civil Docket No.
	*	2:07-CV-139
VS.	*	Marshall, Texas
	*	
	*	June 24, 2009
ABBOTT LABORATORIES	*	1:10 P.M.

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE JUDGE T. JOHN WARD
UNITED STATES DISTRICT JUDGE
AND A JURY

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(Proceedings recorded by mechanical stenography, transcript produced on CAT system.)

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P R O C E E D I N G S

COURT SECURITY OFFICER: All rise.

THE COURT: Please be seated.

All right. Ms. Mullin.

JAMES MARKS, M.D., DEFENDANTS' WITNESS, SWORN

CROSS-EXAMINATION (CONTINUED)

BY MS. MULLIN:

Q. Dr. Marks, just a few more questions on infringement, then we will move on to another subject, okay?

A. Okay.

Q. So I'm going to ask Mr. Ficocello to pull up Plaintiffs' Exhibit 137 again.

These are the studies done by Zehra Kaymakcalan, Dr. Kaymakcalan at Abbott, that Dr. Adams has relied upon in support of his opinions of infringement, right?

A. Yes.

Q. And the studies used cA2 or the antibody in Remicade?

A. That's correct.

Q. And it was competition assays involving Remicade and Humira, right?

A. That's correct.

Q. In one assay, Remicade was labeled; in the other assay, Humira was labeled, right?

A. That's correct.

Q. And those assays showed competition between the two, right?

A. Those assays showed that Humira competes with A2 and that A2 competes with Humira; that's correct.

Q. Okay.

A. Sorry. With cA2. I made a mistake; it was cA2, which is the antibody in those studies.

Q. Now, for purposes of your determination of infringement, you're trying to draw a distinction

between testing with A2 and cA2, right?

A. That's correct.

Q. You were here yesterday in the courtroom when Mr. Conway, one of Abbott's foremost -- former in-house lawyers, testified by deposition, right?

A. I believe I remember that.

Q. And do you recall that what Mr. Conway said was that on December 15th, 2005, after he had gotten notice of the '775 patent was about to issue, he asked Zehra Kaymakcalan for data for the purpose of rendering legal advice about the Centocor patent, right?

A. I -- I believe that's correct. I don't recall, but I'm sure you're right.

Q. I'd be happy to bring up the transcript.

A. No, I'm sure that's correct.

MS. MULLIN: Mr. Ficocello, if you would like to -- it's from yesterday morning's testimony, Page 25 of the transcript, beginning at Line 18.

Q. (By Ms. Mullin) So Abbott's in-house patent counsel, on December 15th, asked Ms. Kaymakcalan for data for the purpose of rendering legal advice about the Centocor patent, right?

A. Correct.

Q. And he gave her the patent that was going to issue as the '775 patent, right?

A. Correct.

MS. MULLIN: And if we can keep going a little bit.

Q. (By Ms. Mullin) And the next day, she gave him the technical information that he needed so that he could provide legal advice regarding the Centocor patents, right?

A. That's correct.

Q. So within a couple of weeks, Abbott's in-house counsel was getting legal advice from an outside attorney about the application, right?

A. That's correct.

Q. And then shortly after that, Abbott's in-house patent counsel realized that it was possible that Centocor was going to sue Abbott for infringement of the '775 patent when it issued, right?

A. That's what it says, correct.

MS. MULLIN: You can take that down. You can blank the screen.

Thank you.

Q. (By Ms. Mullin) I want to shift gears now, and I want to talk about written description of enablement.

A. Okay.

Q. I think you gave opinions this morning on written description and enablement based on the 1994

patent application -- excuse me -- filed by Centocor, right?

A. That's correct.

Q. So we've been through this before, but there was a series of -- there were a series of applications that were filed leading up to the '775 patent, right?

A. That's correct.

Q. The first one was filed in March of 1991, right?

A. That's correct.

Q. Then there were a whole series of what are called CIP applications filed, right?

A. That's correct.

Q. And what it means to be a CIP application is that there was information either added or subtracted from the previous applications, right?

A. That's correct.

Q. And there was the first CIP application filed in March of 1992.

A. Correct.

Q. And a second CIP filed in September of 1992, right?

A. I believe that -- I would need to look at this.

MS. MULLIN: All right. Pull up PX1,

please.

Q. (By Ms. Mullin) This will help. I'm sorry. This is not supposed to be a memory test.

A. There's no way I would remember that.

Q. We'll just do the related patent data.

And you see there were CIP applications filed in 1993 as well.

A. Correct.

Q. And then again, there were a few CIP applications filed in February of 1994, right?

A. Correct.

Q. And the February 1994 date is significant, because, although there were further applications leading up to the application that issued as the '775 patent, in your opinion, none of the later applications added any information relevant to enablement, right?

A. Excuse me. What's the question?

Q. Sure.

Although after February 1994, there were additional applications filed, right?

A. Correct.

Q. It is your opinion that none of the later applications added any information relevant to enablement, right?

A. That's correct.

Q. So just walking up the ladder, it's your opinion that a person of ordinary skill in the art would not be able to make or use human antibodies, based on and at the time that the March 1991 application was filed, right?

A. That's correct.

Q. And it is your opinion that a person of ordinary skill in the art would not be able to make or use human antibodies, based on and at the time that the March 1992 application was filed, right?

MR. LEE: Your Honor, may we approach?

THE COURT: Yes.

(Bench conference.)

MR. LEE: We're in the March 1992 application now and enablement, which I thought is where we weren't going to go. It might be my confusion, but...

THE COURT: Well, I guess she's just trying to confirm that he agreed, that he's of the opinion that none of those earlier applications enabled the patent.

Is that what you're doing?

MS. MULLIN: Uh-huh, just up through '94.

THE COURT: Okay. What's your objection?

MR. LEE: No. I am unclear and I

apologize.

MS. MULLIN: I'm not going to ask him -- I know where you're going to. We're going to go to the '94 application and let him focus on it.

MR. LEE: I just want to make sure we're focused on the same thing.

THE COURT: Well, it looks like to me we could do a catch-all rather than this up-the-ladder thing.

MS. MULLIN: You got it. I was going to stop at '94.

MR. LEE: I was just confused on it.

THE COURT: Well, what confusion do you have, Mr. Lee?

MR. LEE: I -- I had purposely stayed away from any mentioning of the application before '92, because that's what -- and the question whether they were enabled or not. But as long as you won't go into anything before '94, we will be okay.

MS. MULLIN: Actually, I think you showed the '91 application on the screen this morning and had your expert talk about it.

THE COURT: My instruction was you stay within his expert report. His expert report did say none of these applications were enabled, correct?

MR. LEE: True.

THE COURT: Yes.

MR. LEE: And Adams said the opposite, but I'm not going to go there with Adams after Your Honor's ruling.

MS. MULLIN: Nor will I.

THE COURT: Yeah, because Adams says the output, but I ruled the contrary in your favor.

MS. MULLIN: Why is he arguing with me? He won this.

THE COURT: Let's go.

(Bench conference concluded.)

Q. (By Ms. Mullin) Excuse the interruption.

A. No problem.

Q. So let me see if I can lump these together. We have the February 4th, 1994 date highlighted here.

A. Yes, we do.

Q. But it is your opinion that none of the applications, up to and including the February 4th, 1994 patent application filed by Centocor, enabled a person of ordinary skill in the art to make or use human antibodies based on and at the time that each one of these applications was filed; is that right?

A. Not that met the scope of the claims; that is correct.

Q. And the Patent Office, at least through the applications leading up to February of 1994, agreed with you, right?

A. That is correct.

MS. MULLIN: So let's look at DX766, please.

Q. (By Ms. Mullin) I believe this is the prosecution history for the application filed in September of 1992, right? And if we can refer to the page designated as ABT01362404.

This is an office action, right?

A. Correct.

Q. So this is a paper that when the Patent Office is examining an application in deciding whether or not they should allow it to issue, they can send this to the applicant to tell them what they think of the patent application at that particular point in time, right?

A. That's correct.

MS. MULLIN: And if we can go to page ending 411, 404 up to 411, about midway through the page, go down a few lines.

Q. (By Ms. Mullin) What the Patent Office said about the 1992 Centocor patent applications is that the specification does not teach how to produce chimeric antibodies having less than an entire mouse variable

region, right?

A. That's what it says.

Q. What that's really saying is that the specification does not teach or enable how to produce fully human antibodies, for example, right?

A. It says what it says.

Q. Well, a chimeric antibody having less than an entire mouse variable region, in your opinion, could be a fully human antibody, right?

A. Oh, certainly. It could be, yes.

Q. So this is what the Patent Office told Centocor in 1992, but then Centocor went back to the drawing board and added more information in February of 1994 relating to human antibodies, right?

A. There was more information added, correct.

Q. And after that information was added, the next time that Centocor presented claims, submitted claims to the Patent Office asking for the issuance of the patent directed to fully human antibodies, the Patent Office did not reject those claims for lack of enablement; is that right?

A. That's correct.

Q. So before the Patent Office allowed the claims to fully human antibodies to issue, the Patent Office had to determine that they were fully enabled, right?

A. That's correct.

Q. So we've done this a few times, but let's walk through a little bit what was added in February of 1994.

A. Okay.

Q. Let's start actually with what we agree. I know we're going to disagree about one point, but, again, let's figure out where we agree, okay?

A. Great.

Q. So you would agree with me that there was adequate written description support in February of 1994 for a chimeric antibody, right?

A. Yes, I would.

Q. And what that means is that there was adequate written -- written description support for an isolated recombinant anti-TNF-alpha antibody, right?

A. Correct.

Q. And there was adequate written description support for an antibody having a human constant region, right?

A. Correct.

Q. And for an antibody having a human IgG1 constant region, right?

A. Correct.

Q. And for an antibody that competitively inhibits binding of A2 to human TNF-alpha, right?

A. Correct.

Q. And for an antibody that binds to a neutralizing epitope of human TNF-alpha in vivo, right?

A. Correct.

Q. And for an antibody having an affinity of at least 1 times 10 to the 8th liter per mole measured as an association constant as determined by Scatchard analysis, right?

A. Correct.

Q. Okay. So we agree that there is written description support for all of that in February of 1994. And you'd also agree with me that the February 1994 applications enabled the things that we've just talked about.

A. That is correct. Chimeric antibodies, correct.

Q. Having the properties that we've just discussed, right?

A. Correct.

Q. So where we disagree is whether in February of 1994, there was written description or enablement to an antibody having a human variable region.

A. Correct.

Q. A human light chain.

A. Correct.

Q. Or a human heavy chain.
A. Correct.
Q. And that's the only place where you feel there's not adequate written description support or enablement in the February 1994 application, right?
A. That's correct.
Q. And these things, the human variable region, the human light chain, and the human heavy chain, they're all traits of a human antibody, right?
A. That's correct.
Q. And in 1994, among the information added to the specification, was a specific reference in the summary of the invention that indicated that anti-TNF antibodies of the invention included human antibodies, right?
A. The words appear.
MS. MULLIN: Could we please bring up the patent at Column 5, Lines 55 through 59?
Q. (By Ms. Mullin) Actually, before we look at this, would you agree with me, Dr. Marks, that all of the applications from 1994 forward and through the issued patent provide adequate written description report and enablement for at least chimeric antibodies having all the elements of the claims, except for those few that we've specifically identified as relating to

human antibodies?

A. I would say for chimeric antibodies, yes.

Q. And that would include all of the limitations in the claim, except for the specific human variable region, human light chain, and human heavy chain in certain dependent claims, right?

A. That is correct.

Q. So we've seen this before, but in 1994, in February of 1994, in the summary of the invention, the inventors indicated specifically that their invention included human antibodies, right?

A. The words appear.

Q. So the words appear.

And for purposes of written description -- because I want to separate that out from enablement -- you're looking for a written description of the invention, but to support that, you don't actually have to be in possession, physically in possession of every possible version of the invention, right?

A. Not of every possible version, but they were not in possession of human antibodies.

Q. Well, let's just back up a little bit. For a written description, and enablement for that matter, the inventors don't need to be in possession, physical possession, or have actually made any version of the

invention, right?

A. They need to show that they have the invention.

Q. But having the invention is different than having a physical thing that you've made that represents every version, or what we call embodiment of the invention, right?

A. Correct; not every version. But it's clear to me that they don't have human antibodies and does not meet the written description requirement.

Q. So if I understand that -- and you understand the written description requirement to meet that, Centocor didn't even need to say the word human antibodies, right?

A. That's correct.

Q. So they didn't need to say it, but in your opinion, when they did say it, you read that as not including human antibodies?

A. They don't meet the description requirement. There is not sufficient detail.

Q. Okay. But you'll agree with me --

A. I agree with you the words appear.

Q. Okay. And in February of 1994, we talked about this a little bit, and it appears in Column 18, Lines 48 to 53.

MS. MULLIN: Please go down another line. I'm sorry. I probably gave you the wrong line numbers.

Q. (By Ms. Mullin) We talked about this, but Centocor added a reference or a citation to an article that you had written in October of 1993, right?

A. That is correct.

Q. And what this paper talks about in making human antibodies against human antigens using phage display, right?

A. Correct, red blood cell antigens.

Q. And also in the February 1994 applications -- I think we've seen this before -- Centocor added a section entitled, Structural Analogs of Anti-TNF Antibodies and Anti-TNF Peptides, right?

A. Can you bring that up and highlight it just so I can see it?

Q. Sure.

MS. MULLIN: How about Column 3 -- 33 -- I'm sorry -- beginning at Line 7. And it actually continues over to Column 34, Line 25. I'm not sure if you can get all of that, but at least the beginning.

Q. (By Ms. Mullin) Okay. Centocor added this entire section describing structural analogs of anti-TNF antibodies and anti-TNF peptides, right?

A. I think we have the wrong part highlighted.

Q. Okay. I'm sorry. I didn't see the highlighting.

Okay. We'll make the question simple. That section was added in February of 1994, and it describes a way to make structural analogs of anti-TNF antibodies and anti-TNF peptides, right?

A. Excuse me. Now that I've looked at it, can you ask the question again? I'm sorry. I was looking and trying to listen.

Q. Sure.

In February of 1994, there was an entire section spanning more than one column, added to the Centocor patent application relating to or describing structural analogs of anti-TNF antibodies and anti-TNF peptides, right?

A. That's correct.

Q. And in your answers that you were giving in response to questions asked by Mr. Lee, you said, I think, one of the problems with this description is that there weren't models available at the time.

A. Correct.

Q. But actually, the structure for an antibody is generally the same for all antibodies, right?

A. If they share the same -- what we call the same fold. On gross inspection, they share that same

general Y-shape, correct.

Q. And what -- what you're saying is there wasn't -- there weren't -- there wasn't enough information to model the interaction between TNF and the antibody, right?

A. In fact, it's worse than that. There's not even enough information to know what the antibody binding site looks like, let alone model its interaction with TNF-alpha.

Q. Well, years earlier, Eck and Sprang had published an article that give you the exact crystal structure of TNF-alpha, right?

A. I believe that's correct.

Q. And if you look at PX1.

MS. MULLIN: The patent, Page 3, not column -- page -- halfway down on the right-hand column just about, can you find Eck and Sprang?

Q. (By Ms. Mullin) So the Centocor patent actually references the publication that provides the structure or the model of TNF-alpha, right?

A. Yes, it does.

Q. Now, you agree that the portions of the patent specification most susceptible to an interpretation as encompassing fully human antibodies were added in this February 1994 application, right?

A. I'm sorry. I don't understand the question, most susceptible.

Q. Okay. I believe that you have your report that you prepared for this case identified as DX317 in your binder.

A. Yes, I do.

Q. And if you look at Paragraph 262, the last sentence, does this refresh your recollection that in your opinion, the portions of the patent most susceptible to an interpretation as encompassing fully human antibodies were added in February of 1994?

A. Yes, that's what I said.

Q. You agree that the February 1994 application is significant for our purposes, right?

A. I am not sure, again, what you mean by the word significant or purposes. I mean, if you could rephrase the question, I'll answer it.

Q. Now, when you were talking about your general discussion about enablement and the things to consider, you put up something called the Wands factors.

A. Yes.

Q. These are the things you're supposed to look at in considering enablement, right?

A. Correct.

Q. And the first one is the nature of the

invention and the breadth of the claims, right?

A. Correct.

Q. And that's talking about breadth of the claims would be how many -- how many particular, in this case antibodies, are being covered by the patent claims, right?

A. That's correct.

Q. And in this case and actually the more antibodies that you cover, the kind of -- the higher the standard is for enablement, right?

A. Correct.

Q. And you have actually, in this case, agreed that there is only one antibody that meets all the elements of the claims at issue here, right?

A. I don't believe so, because there's only one antibody that -- I don't understand the question.

Q. You've identified CDP571, and you contend that that includes all the --

A. Correct.

Q. You have not identified any other antibody, right?

A. That's correct.

Q. And there's also a reference here to working examples and amount of direction or guidance, right?

A. That's correct.

Q. And I think you mentioned -- excuse me -- that there was no suggestion of specific examples relating to fully human antibodies, right?

A. That's correct.

Q. Now, if you're measuring the affinity of two antibodies, you use the same test whether the affinity you're measuring is of a chimeric antibody or a human antibody, right?

A. You could, yes.

Q. And the patent describes affinity testing, right?

A. Yes, it does.

Q. And the patent also describes competition assays, right?

A. Yes, it does.

Q. And you would use the same competition assay regardless of whether the antibody is chimeric or human or mouse?

A. Yes, you could.

Q. And there are also a number of neutralization assays that are described in the patent. And, again, those assays apply, at least some of them apply, whether you're talking about a mouse antibody, a chimeric antibody, or a fully human antibody, right?

A. That's correct.

Q. And enablement is not based solely on the examples in a patent, right?

A. That's correct.

Q. And enablement does not require the inventors to make, much less commercialize, every possible variation of a product that might be within the scope of the claims to their invention, right?

A. That's correct.

Q. Now, I'm going to jump down to experimentation, because then we're going to come back to Item 3.

A. Okay.

Q. In terms of experimentation, you recognize an invention can be enabled, even if a person is skilled in the art would have to do some experimentation, right?

A. Absolutely.

Q. The experimentation just can't be undue, right?

A. Correct.

Q. And what is undue experimentation is measured by what's usual in the field, right?

A. Correct.

Q. And in this field, as Dr. Salfeld testified yesterday, and you may have also mentioned this morning, taking years of very hard work to develop something is

not unusual, right?

A. In the particular instances here, it would be unusual. It also required multiple inventive steps as well as a lot of hard, hard work.

Q. I'm not sure -- I may have missed the answer.

A. Okay. I'm sorry.

Q. But you and Dr. Salfeld have both testified that in this field, years of hard work to develop something is not unusual, right?

A. It can take years of hard work to develop something in this field correct.

Q. And it's not unusual for it to take that long, right?

A. Correct.

Q. And Item 4 also talks about the relative skill of those in the art, right?

A. Yes, it does.

Q. Because enablement is judged based on someone who comes into the field with the knowledge of someone of skill in the art, right?

A. Correct.

Q. And in this case, that's actually pretty high, right?

A. I think the level of skill of antibody engineers is reasonably high. It's a very technical --

yes, correct.

Q. So that actually means that they come in with a level of -- or a high level and understanding of everything in the field that's published and available, right?

A. I would say that's not true. They would have -- for some technologies, they might have very little actual experience, but, overall, their level of education and experience is high, yes.

Q. Now, I'd like to talk to you about what was available in February of 1994, and this is the state of the art, right?

A. Okay.

Q. And I think you mentioned that in 1992, you were able to generate fully human anti-TNF-alpha antibodies, right?

A. For clarification, do you mean meeting the scope of the claims, or just any old TNF antibodies?

Q. The question was simply, by 1992, you were able to generate fully human anti-TNF-alpha antibodies, right?

A. Yes, but not meeting the scope of the claims.

Q. We'll get to that.

A. Okay. I'm sorry. Anticipation.

THE COURT: It would help the Court so I

wouldn't have to get involved in y'all's exchange if you'd just answer the question. I don't want to be involved any more than I have to.

THE WITNESS: Yes, Your Honor.

Q. (By Ms. Mullin) And when you did that in 1992, you were actually a student working towards your Ph.D., right?

A. That is correct.

Q. And the genetic material that you used to make your fully human anti-TNF-alpha antibodies came from human volunteers, right?

A. That is correct.

Q. That's what you were subscribing in this slide earlier, right?

A. That is correct.

Q. You took blood samples from humans, and then isolated the DNA, right?

A. That is correct.

Q. And the DNA you isolated included the gene that encoded the heavy chair variable region and the light chain variable region of the antibody, right?

A. That is correct.

Q. And you used phage display to express the portion of the antibody that binds to the antigen, right?

A. That is correct.

Q. And when you used phage display, which is one of the methods that you identified this morning as a way to make human antibodies, you did that in 1992 before you had your Ph.D., correct?

A. That's correct. This is work I did as part of my Ph.D.

Q. And that was before February of 1994, right?

A. Yes, it was.

Q. And in the same timeframe, or at least before February of 1994, you were not the only one or the only group to isolate human antibodies against TNF-alpha, right?

A. That's correct.

Q. For example, Dr. Casali -- we heard from him this morning -- was able to isolate human antibodies against TNF-alpha using a different technique; this one, right?

A. That's correct.

Q. That's Dr. Casali.

And he did this in the 1992 to 1993 timeframe, right?

A. That's correct.

MS. MULLIN: I should have done that one with a different color.

Q. (By Ms. Mullin) Okay. And I don't think this came out this morning, but Dr. Casali was at NYU, but he was not affiliated with the group at NYU that worked with Centocor to develop the invention at issue here, right?

A. I believe that is correct.

Q. So he was a separate, independent group working on these things?

A. Correct.

Q. And what Dr. Casali used was Epstein-Barr virus or EBV, right?

A. That's correct.

Q. That's not something you've ever used in your work, right?

A. Correct.

Q. And he was able to isolate human antibodies against TNF, right?

A. That's correct.

Q. Now, I think you and Dr. Salfeld have characterized Dr. Casali's work as -- have characterized it as being a failure, right?

A. That's correct.

Q. And you said that's because the affinity or having the ability to bind and stick to the antibody was too low on these antibodies generated by Dr. Casali,

right?

A. And they were non-neutralizing, so correct.

Q. Well, the non-neutralizing part is often linked to the inability to bind or stick tightly to the antigen, right?

A. It can be.

Q. And we call that the affinity of the antibody to the antigen, right?

A. Yes, we do.

Q. And the issue that you have with Dr. Casali's antibodies is that they were a low-affinity antibody, right?

A. And they were non-neutralizing.

Q. Okay. But, again, the non-neutralizing could come with a higher affinity, right?

A. It could.

Q. And we know from an article that you published in August of 1992 that there were techniques available to affinity-mature, or increase, the affinity of the antibody, right?

A. Yes, there were.

Q. And Dr. Casali's contract actually expired in 1993.

A. I believe that's correct.

Q. And that was before anyone tried to

affinity-mature his antibodies to see if they might be able to get them up to a high enough affinity to neutralize, right?

A. I'm not aware that anyone tried to affinity-mature his antibodies.

Q. So as far as you know, no one ever tried to do what was known in the art to make those antibodies neutralizing, high-affinity antibodies, right?

A. That was not known in the art, how to do that.

Q. Well, it was disclosed in your article.

A. Well, what we disclosed in the article were potential ways to increase the affinity of antibodies using phage display. And we had no idea -- and we provided examples, but we had no idea how widely applicable this was nor the degree to which we would be able to increase the affinity.

Q. You published on it in August of 1992, isn't that right, Dr. Marks?

A. Can you pull that up for me?

Q. Sure. If you'd like to see Plaintiffs' Exhibit 324.

And if you'd actually like to refer to your deposition as well.

A. I'll look at 324.

THE COURT: Well, do you want him to look

at his deposition?

Q. (By Ms. Mullin) I would like for you to look at your deposition as well. It may save you from trying to reread the article now.

A. Okay. Great.

Q. If you'd like to look at Page 255, beginning at Line 20.

THE COURT: Is this the April deposition?

MS. MULLIN: This is the April deposition, so this was just a few months ago.

A. All right. What line?

Q. (By Ms. Mullin) Page 255, Line 20.

If you look at Page 254, you can see that I was asking you a series of questions about Plaintiffs' Exhibit 324.

A. Correct.

Q. This is the article that you published in August of 1992, right?

A. Let me just go back and --

Q. You can refer to your deposition. How about if I do it this way, Dr. Marks.

A. I am referring to my deposition.

Q. Okay. Beginning at Line 15 on Page 254.

QUESTION: Is this an article that was published in August of 1992?

ANSWER: It is.

QUESTION: And it describes your use of filamentous phage to produce antibodies?

ANSWER: It does.

A. Yes, but I published a number of papers, so if you can direct me back which specific paper this is.

Q. This is PX324. And if you can refer to your deposition at Page 255, Line 20.

A. Got it.

Q. I asked you the question: And then referring again to the article that I've just placed in front of you that's marked Plaintiffs' Exhibit 324 --

You answered: Uh-huh.

QUESTION: -- this publication also indicates that you can affinity-mature.

And that means increase the affinity, right?

A. Correct.

Q. By chain-shuffling and/or mutagenesis, right?

A. Correct.

Q. And it describes -- and you explained that it describes a route by which the technology can be applied to increase the affinity of antibodies by chain-shuffling and/or mutagenesis, right?

A. Correct.

Q. Okay. And that was published in August of

'92, right?

A. That's correct.

Q. Okay. I'm going to go a little out of order, because we already have this up here.

But the transgenic mice technology, that was something that was in existence, even if not fully developed, as early as 1992, right?

A. I believe that's correct.

Q. It's actually one of the things that Abbott or its predecessor, BASF, considered, right?

A. That's correct.

Q. And by 1994, there were publications issuing that were detailing the production of fully human antibodies from transgenic mice, right?

A. That's correct.

Q. And you understand that for purposes of enablement, only one of these three methods needs to enable the production of fully human antibodies by February of 1994, right?

A. That's correct.

Q. So let's talk a little bit about Humira development.

A. Okay.

Q. I think you referenced that earlier, and I'm jumping around a bit, so here's the warning I'm shifting

gears.

A. You're keeping me on my toes.

Q. Okay. We've already talked about your development of anti-TNF-alpha antibodies in 1991. Now we've talked about Dr. Casali's development antibodies in 1992 and '93, right?

A. Correct.

Q. And when the relationship between BASF and Casali ended in 1993, Abbott then engaged in a relationship with CAT, or Cambridge Antibody Technology, to work on the Humira project, right?

A. That's correct.

Q. And at the time that Abbott did this in 1993, Dr. Salfeld recognized that the approach by CAT was a proven technology, right?

A. Is that what he said? I don't know.

Q. Okay. We can refer to Plaintiffs' Exhibit 78. I'm sorry. That's my --

And I think if you look at the -- kind of bottom of the first proof of concept.

A. Is it on -- is it on that first page?

Q. It is on the first page, so we're going to bring it to you and make it a little bigger.

A. Okay. That will help. I can see it here, too.

MS. MULLIN: I'm sorry. You've blocked the top of that, Mr. Ficocello.

Q. (By Ms. Mullin) But this was actually a memo that was written by Dr. -- or a report that was written by Dr. Salfeld in September of 1992, right?

A. Correct.

Q. And he gave some testimony about this yesterday as well, right?

A. Yes, he did.

Q. And when in 1992 Dr. Salfeld was talking about the CAT technology, one of the things he said was that CAT has long-standing experience with their approach, right?

A. That's what it says, yes.

Q. And it also indicates that CAT had --

MS. MULLIN: I think we need to go down a little bit further, Mr. Ficocello.

Q. (By Ms. Mullin) Had a very large library, human and heavy -- human, heavy, and light chain library available to it, right?

A. That's what it says, yes.

Q. And if you turn to Page 2 of the same document --

A. Yes.

Q. -- when Dr. --

A. Yes.

Q. Under the title, Humanization of Murine Antibodies.

A. Yes.

Q. When Dr. Salfeld was describing the state of this technology in 1992, he knew that CAT had already successfully humanized murine antibodies.

If you go down a few lines.

CAT has successful humanized murine antibodies.

A. Correct. That's what it says.

Q. And they were able to keep and even improve the binding affinities, right?

A. Correct. That's what it says.

Q. In fact, this was 1992, but CAT had started to advertise in 1991 that it was offering technology that could be used to turn mouse antibodies into human antibodies, right?

A. That is correct.

Q. They were advertising in prestigious scientific journals, right?

A. Yes.

Q. So after this 1992 evaluation between March and July of 1993, CAT actually started to use its antibody gene library in phage display technology for

Humira, right?

A. That's correct.

Q. Okay. Since we've seen enough of my writing, I've asked for some help.

I want to talk about Humira development, and what happened was that in March and July of 1993, CAT started using its antibody gene library and phage display technology for the Humira project, right?

A. That is correct.

Q. So phage display was the first step in the development of Humira, right?

A. Correct.

Q. It took less than six months before the first human antibody binding fragment had been made, right?

A. That is correct.

Q. And one of the antibody binding fragments that they focused on was a fragment designated 4SE3, right?

A. Correct.

Q. And the process of getting from the mouse antibody to 4SE3 was a process of guided selection, right?

A. I believe that's correct, yes.

Q. If you would like to refer to your deposition at Page 292.

A. Thank you.

Q. Beginning at Line 4 to 7, the process of getting from MAK195 to 4SE3 was a process of guided selection, right?

A. Correct.

Q. So we have the first two steps so far in making Humira, right?

A. Correct.

Q. And guided selection is actually a specific type of chain-shuffling, right?

A. Yes, it is.

Q. Okay. So we'll include that.

And then the next step in making Humira in the spring and early summer of 1994 was a series of affinity maturations, right?

A. That's correct.

Q. That's our next step, and through those affinity maturations, 4SE3 became 2SD4, right?

A. That's correct.

Q. Now, this is a year into the project, about a year into the project that it took to get to this point, right?

A. I believe that's correct, yes.

Q. And the affinity of the human anti-TNF antibody that existed at that time was about 3 times 10 to the 9th, right?

A. I believe that's correct, yes.
Q. And that's greater than 1 times 10 to the 8th, right?
A. Yes, it is.
Q. Okay. So after that, for Humira, they actually went through an additional step, and that was off-rate selection, right?
A. That's correct.
Q. So going from 2SD4 to D2E7, that was off-rate selection, right?
A. That's correct.
Q. So we've walked through the steps for developing Humira, right?
A. Yes, we have.
Q. Okay. Then I ask you to turn, please, to PX446.
Do you have that in front of you, Dr. Marks?
A. Not yet. There are a lot of pages.
Q. Just let me know when you're ready.
A. Okay.
Q. This is an article that --
A. I must have -- did you say PX or DX?
Q. PX. I'm sorry. Plaintiffs' Exhibit 446.
A. Okay. I'm sorry. I got 445.
Yes.

Q. This is an article that describes human anti-self antigens with high-specificity from phage display libraries, right?

A. Human anti-self antibodies, correct.

Q. From phage display libraries, right?

A. Correct.

Q. And this was published in February of 1993, right?

A. Correct.

MS. MULLIN: And if you go to the last pages of this reference -- keep going until you get to the list of references.

See the list of references?

I think that might continue on as well.

Q. (By Ms. Mullin) In scientific articles, there's generally a list of references at the end of the article, right?

A. That's correct.

Q. And they identify the other publications or information that's available that's relevant to what they're doing, right?

A. Correct.

Q. And it supports what they're doing and that what they're doing is --

A. That's one of the things it does, yes.

Q. Okay. And in this case for this article that was published in February of 1993, we have the last page up. All of these are references that obviously had to exist before February of 1993, right?

A. Correct.

Q. Okay. If you could turn, then, to Defendants' Exhibit 376.

A. Yes.

Q. This is a published application, right?

A. Yes, it is.

Q. And this discloses guided selection technique, right?

A. Yes, it does.

Q. And this was published in April of 1993, right?

A. That's correct.

Q. Okay. It's an application, not an article, so it doesn't have the same list of references at the back, right?

A. That's correct.

Q. Okay. If you could turn, then, to PX324.

A. Okay.

Q. You recognize this as an article -- it's actually authored by you -- that talks about chain-shuffling, right?

A. Yes, it is. It's a review article.

Q. Okay. And this was published in August of 1992, right?

A. Correct.

Q. And this article also talks about techniques of affinity maturation, right?

A. Yes, it does.

Q. Again, I'm not going to look at it, but at the end of this, there are pages of references listed as relating to what's described here.

A. That's right.

Q. And they were all publications that were available to everyone in the field as of the time that you published this article, right?

A. Yes, they were.

Q. Okay. If you can turn, then, to DX, that's Defendants' Exhibit 419.

A. I'm sorry. DX what? 419?

Q. 419.

A. Yes.

Q. This is another article that talks about affinity maturation of antibodies from a phage library, right?

A. Yes, it is.

Q. And it was also published in April of 1992,

right?

A. That's correct.

Q. And it includes that whole list of references at the back, right?

A. It has a lot of references at the back.

Q. Okay. So let's go to Defendants' Exhibit 425, please.

A. Yes.

Q. This article specifically discusses off-rate selection, right?

A. Yes, it does.

Q. And this was published in August of 1992, right?

A. That's correct.

Q. And this is another article that includes a whole list of references that are at the back, right?

A. That's correct.

Q. Okay. So we just walked through this, but let's see if we can bring it together a little.

These are the five steps that were used to make Humira, right?

A. That's correct.

Q. And as we've indicated, every one of these steps was described in articles, patent applications, or other publications that were available to everybody

working in the field as of February 4th of 1994, right?

A. That's correct.

Q. Okay. Okay. Can we move on then? And if I can ask you to take a look at Plaintiffs' Exhibit 325.

A. Yes.

Q. This is actually a book, right?

A. Yes, it is.

Q. And you wrote a chapter in this book?

A. Yes, I did.

Q. And it's a book on antibody engineering.

A. That's correct.

Q. And the particular chapter you wrote explains how you make antibodies using phage display techniques, right?

A. Uh-huh.

MS. MULLIN: If we can turn to the first page of the chapter.

Q. (By Ms. Mullin) You wrote this, right?

A. Yes, I did.

Q. And it explains phage display, right?

A. Yes, it does.

Q. And it explains how you can use the techniques to affinity-mature or increase antibody affinity, right?

A. Yes, it does.

Q. And this chapter was actually published in

1995, right?

A. That's -- I believe that's correct, yes.

Q. So in 1995, you could have looked at anything or identified anything prior to that time as supporting the description of these techniques that you were providing, right?

A. Excuse me. I missed part of the question.

Q. Sure.

In 1995, everything out there that had been published was available to you, right?

A. To consider to put in this chapter?

Q. Yes.

A. Yes.

Q. Okay. Well then, let's look at the end of the chapter.

MS. MULLIN: And I think maybe we've already highlighted this to help, Mr. Ficocello.

Q. (By Ms. Mullin) At the end of your chapter, in 1995, when you had everything available to you, you listed 54 references in support of your description of the techniques available for making human antibodies, right?

A. That's correct.

Q. And every one of those references was dated in 1993 or before, correct?

A. I'll take your word on that. I can't recall the references I used in 1995, and I haven't looked through this to look and see if that's correct. Probably correct.

Q. Okay. So you wouldn't be surprised if everything that you identified as relevant to your description had been published in 1993 or earlier, right?

A. 1993 or earlier?

That's probably correct. That's correct.

Q. And I know it's not referenced actually in your list of references, but in February of 1994, the Winter Lab published results confirming that higher affinity antibodies could be isolated directly from a phage display library, including antibody fragments binding human TNF-alpha, right?

A. Can you refer me to that reference, please?

Q. Sure.

A. Can you just show me what you're reading from?

Q. Sure. If you can refer to your report, your validity report, at Paragraph 157. I'll let that refresh your recollection, and then I'll ask the question again.

A. What -- what exhibit is that? I'm sorry.

Q. Exhibit 317.

A. And where do you want?
Q. Paragraph 157.
A. I'm sorry. Did you say --
Q. If you'll just read Paragraph 157 of the report that you prepared for this case on validity, and read it to yourself, then I'm going to ask you a question.
A. It's taking me a while to get there. There's a lot to move around up here.
Q. I'm sorry. I have you jumping around.
A. So --
Q. In the Defendants' exhibit binder --
A. Correct.
Q. -- Exhibit 317.
A. Correct.
Q. That's the report that you wrote.
A. Yes, it is.
Q. And if you'd refer to Paragraph 157 and read it to yourself for a minute.
Are you ready for a question?
A. Yes, I'm ready for the question.
Q. In February of 1994, the same time that Centocor filed its patent application --
A. Yes.
Q. -- the Winter Lab also published results

confirming that higher affinity antibodies could be isolated directly from a phage display library including antibody fragments binding to human TNF-alpha, right?

A. That's what it says, correct.

Q. Okay. Now, you understand that enablement is not based simply on what's written in the patent application, right?

A. Correct.

Q. It is based on everything that's available to someone of ordinary skill in the art, right?

A. Correct.

Q. And that would include everything we've talked about, except for actually your book chapter.

A. Correct.

Q. So all of that information, including the 54 references that support what you're describing in your book chapter, would have been available to somebody of ordinary skill in the art in February of 1994?

A. Correct.

Q. And they could have used that information, right?

A. They certainly could have used that information, correct.

Q. In fact, the February 1994 Centocor patent application explicitly said that the antibodies of the

invention could be produced by recombinant techniques known in the art, right?

A. That's what it says, correct.

Q. So just so I'm clear, a person of ordinary skill in the art with all of the information in front of them, including all of these articles that we've discussed, the 54 references in your chapter, given all of that, it is still your opinion that a person of ordinary skill in the art could not make -- or would not be enabled to make human antibodies as claimed based on the February 1994 application, right?

A. That's correct.

Q. Okay. Actually, in your opinion, somebody of ordinary skill in the art would not be able to make or use human antibodies even as late as July of 2002, right?

A. Not without undue experimentation, that's correct.

Q. So you're saying that even as of July of 2002, when you had made human anti-TNF antibodies a decade earlier, that someone of ordinary skill in the art could not have done that 10 years later, right?

A. This is very technically challenging technology. That's correct. That's what I -- that's what I said.

Q. So I'm going to go back and clean up a little bit, and then we'll move on to another subject.

There's two more things that I'd like to talk about in connection with the 1994 application.

The 1994 application did actually disclose a human variable region, right?

A. Excuse me?

Q. The 1994 Centocor patent application actually expressly disclosed human variable regions, right?

A. It uses the word. It doesn't describe them.

Q. Okay. You'll agree with me that the February 1994 application says human variable regions.

A. Yes.

Q. And you'll agree with me that the 1994 February application filed by Centocor also expressly refers to human IgG1 constant regions, right?

A. Yes, it does.

Q. Okay. Okay. We're going to shift gears. Warning.

A. That doesn't help much with the two big binders, but...

Q. Okay. Well, I'm going to talk now about Adair 1992, which is DX361.

A. Okay.

Q. So if you want to find that before we start,

that's --

A. Pardon. DX3 --

Q. 361. And then you won't have to shuffle.

A. I have it.

Q. Okay. I think you just misspoke, but when you testified about this earlier today, you said that this was a patent that issued in July of 1992, but that's not right.

A. No, that's not correct. It was published in July 9 of 1992.

Q. Right. It's actually an application that was published in July of 1992?

A. That's correct.

Q. Okay. It had not issued as a patent?

A. No, it had not.

Q. Okay. And this is one of the references that you said -- or this is the reference that you say anticipates the asserted claims in this case, right?

A. That's correct.

Q. Now, you know that this reference was actually considered by the Patent & Trademark Office before they allowed the '775 patent to issue, right?

A. I believe that's correct.

MS. MULLIN: Can we pull up PX1, please.

Q. (By Ms. Mullin) This is the patent, and on

Page 2, toward the bottom of the list, there's a reference there to W09211383. It's actually sixth from the bottom. 92 slash --

A. Got it.

Q. There you go. That's the Adair 1992 application, right?

A. Yes, it is.

Q. So that was one of the -- one of the things that the Patent & Trademark Office expressly considered before it allowed the '775 patent to issue, right?

A. Yes, it was.

Q. And so the Patent & Trademark Office considered whether the Adair reference anticipated the asserted claims in this case and determined that it did not before it allowed the '775 patent to issue, right?

A. I don't know what the Patent Office did, but they read -- they read -- they considered the patent, yes.

Q. Okay. So they considered -- not the patent. They considered the --

A. The application. Sorry.

Q. Okay. So to be clear, the Patent & Trademark Office considered this Adair 1992 reference and determined that the '775 patent claims could issue.

A. Correct.

Q. And you understand, for purposes of your anticipation analysis that every single element of the asserted claims have to be present in Adair, right?

A. That's correct.

Q. If there is even a single element of the claim that is missing from Adair, then there is no anticipation, right?

A. That's correct.

Q. I think you actually used two of these charts with Mr. Le, but I'm going to refer to one of them, and we'll just talk about the difference, okay?

A. Okay.

Q. So Claims 2 and 3 are identical to Claims 14 and 15, except that the latter claims specify that the human constant region is an IgG1 constant region, right?

A. That's correct.

Q. So if we just refer to Claims 13, 14, and 15 here, we have all of the elements that are at issue here, right?

A. Correct.

Q. Okay. So let's look at the first one. Claims -- Claim 13 and then 14 and 15 require that the antibody has a human IgG1 constant region, right?

A. Correct.

Q. CDP571 does not have a human IgG1, right?

A. CDP571 has an IgG4 constant region.

Q. And Adair actually says that IgG4-type antibodies are used when the antibody is intended for blocking TNF activity, right?

A. That's what it says.

Q. And the asserted patent claims also require that the claimed antibody binds to a neutralizing epitope of human TNF-alpha in vivo, right?

A. That's right.

Q. And now, what this is talking about, in vivo means in the body, right?

A. That's correct.

Q. So it's talking about binding to human TNF-alpha in a human body, right?

A. It says that it binds to a neutralizing epitope of human TNF-alpha in vivo, correct.

Q. Okay. So just for shorthand, we'll assume that it's a neutralizing epitope, but it has to be a neutralizing epitope in the human body with human TNF-alpha, right?

A. No. I believe it has to bind to a neutralizing epitope of human TNF-alpha in vivo, which means in an animal. So it could be human TNF-alpha in another animal besides a human.

Q. Okay. Well, the only studies done with CDP571

that are reported in Adair were done in a baboon, right?

A. That's correct.

Q. And that used baboon TNF-alpha, right?

A. The baboon would have -- would have baboon TNF-alpha, not human TNF-alpha. They are essentially the same in sequence.

Q. Did Adair 1992 report any testing of CDP571 in a human person for binding to human TNF-alpha in vivo?

A. In a human, no.

Q. Did they do any in vivo assays to demonstrate that human TNF-alpha is neutralized in vivo by CDP571?

A. In humans? Is the question in humans?

Q. Is there anything disclosed in the Adair reference, any test, testing, neutralizing human TNF-alpha in vivo?

A. Yes. There are tests looking at neutralizing -- oh, they're not neutralizing human TNF-alpha; in humans.

Q. Okay. And, in fact, the tests that were done with CDP571 in the baboons were done with an antibody that had an IgG4 constant region, right?

A. That's correct.

Q. And the same is true for the affinity measurements. They were the affinity measurements of an antibody of an IgG4 constant region, right?

A. That's correct.

Q. So then let's talk a little bit about the competitively inhibits limitation.

A. Okay.

Q. You said that you relied on testing done by an independent laboratory.

A. That's correct.

Q. And the person who -- or the laboratory is run by a gentleman by the name of Dr. Kincaid?

A. That's correct.

Q. That's Randall Kincaid, right?

A. That's correct.

Q. And that testing was done in the last six months or so, right?

A. I believe that's correct, yes.

Q. And I think your counsel asked you this, but you understand that your burden here is to prove anticipation by clear and convincing evidence, right?

A. That's correct.

Q. So when you were giving your opinions on invalidity, you understood that those opinions had to be based on clear and convincing evidence, right?

A. Yes, I did.

Q. But before forming your opinions, you never even talked to Randall Kincaid about the testing done in

his laboratory, right?

A. That's correct.

Q. And Dr. Kincaid -- that's Randall Kincaid -- he didn't actually do most of the tests himself, right?

A. He did not physically -- that's correct.

Q. Most of the tests were carried out by his brother, Barry Kincaid, or his office assistant, Brenda Capelik, right?

A. That's correct. I actually don't know what her title was, but those are the two people that did the testing.

Q. And when you relied upon the test done by Barry Kincaid -- and I think you said this is the kind of test that you would normally rely on, right?

A. Correct.

Q. When you relied upon the test done by Barry Kincaid to reach your conclusions, you did not know what kind of education or informal training Barry Kincaid might have that could qualify him to do that kind of testing, right?

A. That's correct.

Q. And the same is true for Brenda Capelik. She was responsible for some of the testing.

A. That's correct.

Q. And the tests that were done in Dr. Kincaid's

laboratory that you relied upon were competitive ELISA assays, right?

A. Correct.

Q. But when you were reaching your conclusions, you did not know if Randall or Barry Kincaid or Brenda or anyone else at Veritas had ever done a competitive ELISA assay before they did the one that you relied on, right?

A. That's correct.

Q. And, in fact, you reviewed Dr. Kincaid's deposition, correct?

A. Yes, I did.

Q. And what he said during his deposition was that he did not recall having ever previously done the kind of competitive ELISA that he was asked to do by the Abbott attorneys, right?

A. That's what he said, that's correct.

Q. Now, in terms of the procedure that was used for the testing that you relied upon --

A. Yes.

Q. -- you told me during your deposition that you were under the impression that Randall Kincaid was heavily involved in developing that protocol, right?

A. That's probably what I said, yes.

Q. But that's not true, right?

A. I -- I don't actually know to this day who actually contributed what part to that protocol.

Q. Well, what Dr. Kincaid said during his deposition -- if you'd like to see a copy, we can certainly bring one up -- was that it was actually one of the Abbott attorneys, Henry Wixon, who prepared the protocol, who came up with the procedures for the test and gave it to him to perform, right?

A. Yes. That's what he said.

Q. And the protocol that they gave him required him to biotinylate the A2 for the assays, right?

A. That's correct.

Q. And that means that you're actually modifying, you're adding molecules to the A2, right?

A. That's correct.

Q. You're adding biotin to molecules, right?

A. That's correct.

Q. And it was definitely not your idea to biotinylate the A2, right?

A. I played no role in the development of the protocol.

Q. And we're talking about A2, and that is a murine antibody, correct?

A. Correct.

Q. It is not a chimeric antibody, right?

A. No, it is not.

Q. But you know from reading Dr. Kincaid's deposition transcript that there may have been an error or a mixup with the sample that he thought was A2, right?

A. I believe that was in the report, and he clarified it in his deposition.

Q. So when he was preparing the report that you relied upon that talked about the testing that he had done, what he indicated was that the A2 he used was a chimeric antibody, right?

A. That it may have been, and then he corrected it in his deposition.

Q. He corrected it in his deposition?

A. That he was working -- that he believed he was working with a mouse antibody.

Q. But he didn't say that -- he didn't correct in his deposition the report prepared at the time that he was doing the test that he indicated, contemporaneously with doing the test, that he thought he was using an antibody that was not A2, right?

A. He didn't change his written report. He corrected what he said in his report --

Q. Okay.

A. -- at his deposition.

Q. So there were things that you could have done or Dr. Kincaid could have done to make sure that he had the right sample, that he was actually testing A2, right?

A. Correct.

Q. So he could have, for example, tested the affinity?

A. He could have.

Q. And we know the affinity of A2 is from the patent, right?

A. Yes, we do.

Q. And we know what the neutralization activities are from the patent, right?

A. Yes, we do.

Q. So he could have tested those things to see if the sample that he might have mixed up was actually A2, right?

A. That's correct.

Q. And the sequence information is also available in the patent. I think you pointed it out. So he could have also verified that way that he hadn't mixed up the sample, right?

A. Yes, he could have.

Q. And for the CDP571 sample that he used, that sample was more than 15 years old, right?

A. That's correct.

Q. And actually, it had an expiration date of September 1994.

A. That's correct.

Q. And he could have done tests to see if what he had that he thought was the CD -- or the characteristics of the CDP571 sample that he had, right?

A. He did.

Q. Or he could have done things like the affinity measurements that are described in the Adair reference, right?

A. He could have.

Q. He could have tried to mimic the neutralization activities that were described in the Adair reference, right?

A. He could have.

Q. And if he had done those things, he would have known if what he had had the same functional characteristics as the antibody that's described in the Adair 1992 reference, right?

A. That's correct.

Q. But he didn't do that, right?

A. No, he did not.

Q. Okay. So you rely on the tests done in

Dr. Kinkaid's laboratory as providing clear and convincing evidence that CDP571 competes with A2 regarding to TNF-alpha, right?

A. Yes, I do.

Q. Now, Dr. Kincaid has said that you cannot rely on these tests for that purpose, right?

A. No, he did not.

MS. MULLIN: Could you please hand...

MR. LEE: May we approach, Your Honor?

THE COURT: Yes.

(Bench conference.)

MR. LEE: I guess I want to make sure this is a portion of his deposition transcript where he gave the errata sheet -- they gave an errata sheet after Your Honor rendered your claim interpretation. Can we just make sure he has both of them up there?

MS. MULLIN: Sure.

MR. LEE: Okay.

MS. MULLIN: I'll make sure that he does.

MR. LEE: Okay.

THE COURT: Okay.

(Bench conference concluded.)

MS. ELDERKIN: May I?

THE COURT: Please do.

THE WITNESS: Thank you.

Q. (By Ms. Mullin) Dr. Marks, can I refer you, please, to Dr. Kincaid's deposition transcript at Page 251, Line 13?

A. Yes.

Q. You considered Dr. Kincaid's deposition before you gave your opinions in this case, didn't you?

A. Yes, I did.

Q. And Dr. Kincaid was the one who had the test done in his laboratory under his direction, right?

A. That's correct.

Q. And what Dr. Kincaid said during his deposition, when he was under oath, beginning at Line 13: So if I understand correctly -- this was the question: If I understand correctly, you have not given conclusions in any part of your report about whether any two antibodies compete with each other for binding to TNF-alpha; is that correct?

A. Correct.

Q. The answer that Dr. Kincaid gave was, Compete, no, because it's not an appropriate assay, in my opinion, for competition, right?

A. That's correct. That's what he said.

Q. And if you can refer, then, to Page 253 of Dr. Kincaid's deposition.

A. Yes.

Q. He was asked a question, beginning at Line 5 and going through Line 11 with the answer, he was asked the question: So sitting here today, you have not formed an opinion as to whether any of these antibodies compete with each other for binding to TNF-alpha; is that right?

ANSWER: I believe I indicated that I don't believe this. The collected data that I have lends itself to evaluating competitive binding.

A. Correct. That's what it says.

Q. Now, this was the testimony that Dr. Kincaid gave when he was under oath on April 2nd, 2009, right?

A. Correct.

Q. And I -- I don't have it in front of me, but you're going to have to help me, because what was just handed to you at the request of your counsel was a sheet that was provided after Dr. Kincaid's deposition, right?

A. Correct. That was his opportunity to correct errors in the deposition, correct.

Q. Right. So what he said under oath on April 2nd, 2009, was what we just read, right?

A. That's correct.

Q. And then a few weeks later, he changed his answers to those two questions, right?

A. That's correct.

Q. So instead of saying, Compete, no, because it's not an appropriate assay, in my opinion, for competition -- and that was in response to the question as to whether he drew any conclusion that A2 antibodies compete together --

A. Correct.

Q. -- he changed it to: Compete for the same epitope, no, because it's not an appropriate assay, in my opinion, for competition for the same epitope, right?

A. That's correct.

Q. So he changed -- and he changed his other answer similarly, right?

A. That's correct.

Q. So after the deposition, after he was no longer under oath --

MR. LEE: Well, I object, Your Honor. The errata sheet --

THE COURT: I sustain the objection.

A witness has an opportunity to change any answers, and they're considered under the same oath as -- legally, under the same oath as at the time the deposition was given.

Let's move on.

Q. (By Ms. Mullin) You know that Abbott is not bringing Dr. Kincaid here to testify, right?

A. I believe that's correct.

Q. So the jury can't hear Dr. Kincaid's opinion in person, right?

A. That's correct.

Q. Okay. You've given a number of opinions here today as a person of ordinary skill in the art, right?

A. Yes, I have.

Q. Okay.

A. I've given a number of opinions here today as an expert witness. Excuse me.

Q. Okay. So that's a distinction, right?

A. Yes, it is.

Q. Let's go through that a little bit.

You have provided a definition of a person of ordinary skill in the art, right?

A. Correct.

Q. This is the definition that you provided, right?

A. Correct.

Q. Okay. And that would be someone who was qualified to evaluate, consider, and give opinions about matters within the '775 patent, right?

A. That person is not an expert; that's a person of ordinary skill in the art. That's what this -- the standard that would be -- one would be held to for

enablement.

Q. Okay.

A. I didn't understand the question, I guess.

Q. That's okay.

A patent specification in the claims are written for somebody that we call a person of ordinary skill in the art, right?

A. Correct.

Q. So it's a fictional -- it's a fictional person, but it's somebody who comes there with all -- I know you're a real person, but it's somebody who -- the idea is that they come forward with all the information, like the things we've been talking about today, right?

A. That's correct.

Q. And you have defined a person of ordinary skill in the art to have a Ph.D. degree or equivalent experience, right?

A. Correct.

Q. In molecular biology or a related discipline, right?

A. Correct.

Q. Including a few years of experience in the field of antibody technology, right?

A. Correct.

Q. So the experience part that's required to be a

person of ordinary skill in the art is experience in the field of antibody technology, right?

A. Correct.

Q. So now I'm going to borrow some of Mr. Lee's questions.

You have not identified the person of ordinary skill in the art in your definition as someone who has isolated an anti-TNF-alpha antibody, right?

A. That's correct.

Q. You have not identified the person of ordinary skill in the art to be required to have isolated a mouse antibody, a chimeric antibody, or a fully human antibody, right?

A. That's correct.

Q. It's kind of like the quarterback. They may never actually play in the position of wide receiver, but they still know exactly the route that the wide receiver is going to run on every play, right?

A. And they never run it as well as the guy who's supposed to be in there.

Q. Okay. Well, let's go back, though, because you've made a distinction between an expert and a person of ordinary skill in the art.

You understand that the opinion on enablement has to come from someone of ordinary skill in the art,

right?

A. I understand that the requirement is that a person of ordinary skill in the art would be able to read the patent and know that they have the invent -- or know how to make the invention, correct.

Q. So that's the person who judges whether or not there's enablement, the person of ordinary skill in the art, right?

A. No. I think that's the person that -- for whom the patent needs to be enabled, the person that needs to make a -- to know that they have it, to know that it works.

Q. So in February of 1994, you did not consider yourself to be a person of ordinary skill in the art, right?

A. February of 1994. I was just thinking.

So by that definition, I would not meet the -- sorry.

By that definition, I would be a person of ordinary skill in the art, by that definition.

Q. Okay. Would you like to refer to your deposition at Page 25, Line 12?

A. Sorry. Which deposition?

Q. Your April deposition, just a few months ago.

A. So then where to go in that?

Q. Sure. Page 12. I'm sorry. That's the wrong page. Page 25.

A. Yes.

Q. What you told me during your deposition, that by the time you got your Ph.D. in 1992, you stopped being a person of ordinary skill in the art, right?

A. That's what I said.

Q. That's what you said during your deposition, right?

A. That's correct.

Q. Okay. By the time you got your Ph.D., you considered yourself to be a world renowned expert?

A. In some aspects of the technologies, yes.

Q. And that opinion continues through today, right?

A. That's correct.

Q. So we can't separate what opinions you gave today as a person of ordinary skill in the art as opposed to a person of extraordinary skill in the art; is that right?

A. Yes, we can.

Q. I'm sorry. Could you refer to your deposition at Page 300?

A. Yes.

Q. Beginning at Line 13.

A. Yes.

Q. At your deposition, I asked you the following question: Dr. Marks, to follow up, when you were giving your declarations or your expert reports in this matter -- and that's the subject matter that we've been describing today, right?

A. That's correct.

Q. -- were you preparing then both as a person of ordinary skill in the art and also a person of extraordinary skill in the art?

ANSWER: I don't see how the two would be separable since both are contained within me.

QUESTION: So how will we separate out which of these opinions will be held by a person of ordinary skill in the art as opposed to a person of extraordinary skill in the art?

ANSWER: You'd have to ask someone who is an ordinary -- person of ordinary skill in the art.

A. That's what I said.

Q. And just to be clear, I think you mentioned during your direct testimony, you have received at least $2.7 million based on sales of Humira, right?

A. That's correct.

Q. And you're going to continue to receive $20,000 or so a year for the next few years?

A. That's correct.
Q. As long as Humira continues to be sold, right?
A. Correct.
Q. And that is actually in addition to what you're being paid to be an expert in this litigation, right?
A. Yes, it is.
Q. Okay.

MS. MULLIN: Pass the witness, Your Honor.

THE COURT: Mr. Lee?

MR. LEE: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. LEE:

Q. Good afternoon, Dr. Marks.
A. Good afternoon.
Q. Let's start from the end and work back. There was some discussion between Ms. Mullin and you about persons of ordinary skill in the art and expert witnesses.

Do you remember that?

A. Yes, I do.
Q. And you said that for the purposes of this trial, you are an expert witness.
A. That is correct. I am appearing as an expert

witness.

Q. And are you testifying as to what would have been known or disclosed to one of ordinary skill in the art?

A. Yes, I am.

Q. So as an expert witness who's giving an opinion as to what one of ordinary skill in the art would know or not know?

A. That's correct.

Q. Okay. And is that the function that you're performing?

A. Yes, it is.

Q. Now, there was some question about the testing by Dr. Kincaid. Is the Veritas Laboratory a reputable laboratory?

A. Yes, it is.

Q. Did you review the protocol?

A. Yes, I did.

Q. Did you review the results?

A. Yes, I did.

Q. Now, you were asked a question about the sample being one from September 1994. Do you remember that?

A. Yes, I do.

Q. And we're focused on the 1994 period here,

correct?

A. That's correct.

Q. With an old sample, what's the most likely effect? Are you going to see more inhibition or less?

A. You would see less inhibition.

Q. And with this old sample, what did you see?

A. We saw complete inhibition.

Q. Satisfying --

A. Complete competition.

Q. Now --

A. We saw that it competes with A2 -- completely competes or almost completely competes with A2 for binding with TNF.

Q. Now, there was some question and answer about Dr. Kincaid's testimony, and His Honor mentioned that witnesses have opportunities to read their depositions after they're taken.

You remember that?

A. Correct, I do.

Q. And just so we all understand, what happens is, you sat in a room with Ms. Mullin for a couple of days, correct?

A. I only sat -- well, I sat there for a whole day twice.

Q. Right. And a reporter was taking down

everything that everybody said just as the court reporter is today, correct?

A. That's correct.

Q. And the rules that govern the proceedings in this Court say, after all that occurs, a transcript is given to the witness, correct?

A. That's correct.

Q. The witness can read it.

A. That's correct.

Q. And the witness can make corrections.

A. That's correct.

Q. And you did that, correct?

A. Yes, I did.

Q. And Centocor's witnesses did that, correct?

A. I assume they did.

Q. All right. Now, let's go to the Adair publication.

Now, to break the issues down, there was enablement, written description, and Adair, correct?

A. Correct.

Q. And Adair was the basis for which opinion of yours?

A. Anticipation.

Q. Now, Ms. Mullin asked you about some differences, IgG4 versus IgG1.

A. Correct.

Q. Did Dr. Adams, in his expert report, identify any of those as differences between Adair and the claims?

A. No, he did not.

Q. Now, what Ms. Mullin did is, she read you a portion of the Adair patent application about IgG4.

Do you remember that?

A. I do.

MR. LEE: Could I have Defendant's Exhibit 3661, please, on the screen, Page 27.

Q. (By Mr. Lee) I'm not sure if it's in your notebook or not, but I'm going to put it on the screen.

A. It is.

Q. Would you turn to Page 27?

A. I have.

MR. LEE: Now, could we have the last sentence of the first full paragraph blown up?

Q. (By Mr. Lee) Do you see the sentence that begins, It will be appreciated?

A. Yes, I do.

Q. Would you read that to the jury and then explain to the jury what that says about IgG1, which is explicitly referred to in the claim.

A. So this sentence says, It will be appreciated,

however, that human constant region domains of other types and isotypes, for example, IgG1, IgG2, and IgG3, could also have been used without significantly altering the procedures described.

Q. Now, this specifically mentions IgG1, correct?

A. Yes, it does.

Q. And did you consider that in forming your opinion of anticipation?

A. Yes, I did.

Q. Ms. Mullin asked you whether -- well, said, well, the Patent Office had Adair, and it allowed the patent to issue, correct?

A. That's correct.

Q. And you know from your own experience that the patent prosecution procedure is a private one between the applicant and the Patent Office, correct?

A. That's correct.

Q. Did -- when the Patent Office considered Adair, were there any tests of any kind on competitive inhibitions between Adair and A2?

A. No.

Q. So that the information that would be needed to determine whether Adair anticipated or not was not before the Patent Office.

A. That's correct.

Q. Did you have that information that the Patent Office didn't have?

A. Yes, I did.

Q. All right. Now, let me go to --

MR. LEE: Do I hit the bottom button to use the ELMO?

COURTROOM DEPUTY: Cam doc.

MR. LEE: Got it. Thank you.

Q. (By Mr. Lee) Let me put on the screen -- try to put on the screen the chart that Ms. Mullin did. And I think the suggestion was that there was all of this information out there, correct?

A. Correct.

Q. And one of ordinary skill in the art could have just put it all together.

A. Correct.

Q. And that Dr. Salfeld should have put it all together.

A. Correct.

Q. Well, let's -- let's go through this.

Are the words guided selection mentioned anywhere in the patent?

A. No, they're not.

Q. Are the words chain shuffling mentioned anywhere in the patent?

A. No, they're not.
Q. Are the words affinity maturation mentioned anywhere in the patent?
A. No, they're not.
Q. Are the words off-rate selection mentioned anywhere in the patent?
A. No, they are not.
Q. And if you look at the references she cited, DX4 -- 376, 324, 324 (sic), and 425, did the patent mention any of those references?
A. No, it did not.
Q. There was one reference the patent did mention, and that's DX446?
A. That's correct.
Q. Whose publication is that?
A. Mine.
Q. And it's based upon work you were doing, correct?
A. That's correct.
Q. So tell the Ladies and Gentlemen of the jury, when you were working in the field, when Dr. Salfeld was working in the field in 1991, 1992, and 1993, was this as simple as just taking four or five concepts that had been written about and putting them in the right order?
A. No, it was not.

Q. What was it instead?

A. It was to -- as you heard from Dr. Salfeld, in order to deploy these technologies -- use these technologies, based on the available publications in the field, it really would take experts working a long period of time doing much, much hard work, what would be defined as undue experimentation.

Q. And for the people who were successful in the field of making fully human antibodies within the scope of the claims, did it require hard work, plus innovation?

A. Yes, it did, significant amounts of innovation.

Q. And how do you know that?

A. I know that from reading the work that they have done, and I know that because I was actively involved in the field, discovering the technology.

Q. Now, Ms. Mullin asked you some questions at the end attributed to a variation of mine, and it was assume the person of ordinary skill in the art, correct?

A. Correct.

Q. Would they have made a murine antibody? Do you remember that?

A. Yes.

Q. Would they have made a fully human antibody?

A. Yes.

Q. The question is not whether they had this person of ordinary skill in the art; was there enough in the patent to teach them how to do it, correct?

A. Correct.

Q. And in your view, if you take all of these 53 references, all of this information that's on the screen right now, would this person of ordinary skill in the art have been able to make a fully human antibody, falling within the scope of the claims, based upon the disclosure of the specification and whatever else they had?

A. No, absolutely not.

Q. And why not?

A. Because it would have required undue experimentation. As -- I mean, I hate to repeat myself, but these were very early stage technologies with a lot of innovation required on an ongoing basis, and there just wasn't enough disclosed in these early publications.

There were other things that needed to be invented. We needed to learn how to increase the library size. We needed to do -- we needed to learn how to do a much better job of affinity maturation.

We needed to learn -- as Dr. Salfeld

described, when you do affinity maturation, how to find the very rare needles in that haystack. You still have to find the antibodies.

So there was just a lot of additional innovation that was required.

Q. Now, you were referred to your 1992 publication concerning affinity maturation?

A. Correct.

Q. And I think the question to you was, well, why couldn't you just take that and use it with Dr. Casali's B-cells, correct?

A. Correct.

Q. Would you explain to the jury why you can't take a work in phage display and just turn it over into Dr. Casali's pioneering work on B-cells?

A. So the biggest problem would have been, there were no neutralizing antibodies there so that even if you could have affinity matured them, it wouldn't have mattered. You could have made the affinity as high as you wanted to make it, and it wouldn't matter if it doesn't bind to the right place.

Human -- humans and human B-cells would not want to make antibodies that would neutralize their whole -- their TNF in their bodies. And the reason is, we need TNF to wake up our immune system.

So, generally speaking, those antibodies do not exist in our bodies. So they probably weren't there.

Even if they were there, we did not know at the time how to take antibodies of such low affinity and increase their affinity hundreds of times to get to antibodies that would meet the scope of the claims.

Q. All right. And just to put us all in context, when you were doing this work was back in the early '90s when there wasn't even e-mail, voice mail, faxes, right?

A. We might have had some rudimentary type of e-mail. I -- I can't recall what electronic -- I can tell you it was really hard to write a paper at that time because of the computing power available.

Q. Now, we're talking about this issue of -- these issues of enablement and written description, and Ms. Mullin asked you, well, you understand that it's not required that the inventors disclose every possible variation in a commercial product.

Do you remember that?

A. I remember that.

Q. In your understanding, that's not required correct?

A. That's correct.

Q. Would it have been helpful to you if the

inventors had disclosed a single example of making a fully human antibody within the scope of the claims?

A. It would have been very important.

Q. Now, as you discussed enablement and written description, there was a mention of something called a CHO cell?

A. Correct.

Q. A Chinese hamster ovary cell?

A. That's correct.

Q. Would you explain to the jury just what that is and how it's used in the process of producing a fully human antibody?

A. So you can think of Chinese hamster ovary cells as factories. They have turned out to be very good cells to make antibodies in. And so one can make mouse antibodies in hamster cells, chimeric, humanized, or human.

So in the case of Humira, it is made in Chinese hamster ovary cells, because that's the standard manufacturing platform that the industry uses.

However, for safety reasons, the FDA requires that many purification steps be employed to ensure that there are no hamster proteins or hamster DNA or even other types of DNA in the drug product, and then they require the companies to show them, by very extensive

testing, that there are no hamster parts in the product.

MR. LEE: Can I have Claims 1 and 2 of the '775 patent on the screen?

Q. (By Mr. Lee) Now, again, I'm focusing --

MR. LEE: That's great. Thank you.

Q. (By Mr. Lee) Again, I'm focusing on the written description and enablement issues.

Do you have those in mind?

A. Yes, I do.

Q. And this is part of the bargain with the Patent Office. If you want a patent, you have to give enough information to provide a written description and enable, correct?

A. Correct.

Q. Now, looking at Claims 1 and 2, Ms. Mullin asked you whether different parts of it were satisfied by a chimeric antibody.

Do you remember that?

A. Yes, I do.

Q. And then said -- and there's a few places where it mentions human, and you think that they're not enabled or described as required, correct?

A. Correct.

Q. If you look at Claim 2 --

A. Yes.

Q. -- which includes all of Claim 1, does it require a humanized antibody?

A. Yes, it does.

Q. And is it a human or humanized antibody that has all the elements of 1 and 2?

A. Yes.

Q. You can't take some elements from a chimeric and some elements from a human, can you?

A. No, you can't.

Q. All right. So you want to find out if the chimeric is enabled, you look at Claims 1 and 2 and figure out if that chimeric has all of it, correct?

A. Correct.

Q. But for fully human, what do you do?

A. You do the same thing. You would look at all of the elements of the claim and see that that antibody met all of the elements of the claim.

Q. Do you have your expert report that Ms. Mullin read -- asked you to read from? And this would be your initial report.

A. What's the exhibit number?

Q. I'm not sure.

MS. MULLIN: It's PX317.

MR. LEE: PX317. Thank you.

A. Got it.

Q. (By Mr. Lee) Now, Ms. Mullin asked you to turn to Page -- Paragraph 262, and she read you a portion.

Tell me when you're there.

A. I'm there.

Q. And she read you a portion of Paragraph 262?

A. Yes.

Q. This concerns the written description requirement?

A. I believe that's correct.

Q. Would you go down to Paragraph -- to Paragraph 264, just a few lines down from where she read and read to the jury what your conclusion was on written description.

MS. MULLIN: Objection, Your Honor.

MR. LEE: I'm just trying to put in context the portion that she read.

THE COURT: Well, it's your objection. If he wants to explain his answer, he can explain his answer. He can't read her -- that's for cross-examination, counsel.

MR. LEE: Fair enough.

Q. (By Mr. Lee) Would you explain to the jury the context of the most susceptible language that Ms. Mullin read to you?

A. So what I meant was that the language that

most -- that could most support claims to human antibodies were in the most recent patent, the February 1994 patent. That's what I meant.

Q. And with all that language considered, what conclusion did you reach?

A. That there's not an adequate written description.

Q. Now, Ms. Mullin asked you about the fact that the PTO, the Patent Office, looked at the '94 application and later applications and allowed the '775 patent.

Do you remember that?

A. That's correct. I remember that.

Q. And you've reviewed the file history?

A. Yes, I have.

Q. Now, in the file history, was the Patent Office told about Centocor's test on the fully human antibody 7.T.1?

A. I don't recall actually.

Q. Were they told about the Casali test?

A. I believe -- one of the earlier applications, I believe so.

Q. Were they told about Dr. Le's testimony concerning what work he had done?

A. His testimony?

Q. Yes.
A. No. No.
Q. Were they told about the work that you had done in 1991 where you had been tried -- you tried and had been unsuccessful?
A. No.
Q. Were they told about Dr. Salfeld's work?
A. No.
Q. Were they told about Dr. Ghrayeb's testimony that Centocor had no solutions for the problems identified in the application for fully human antibodies?
A. No, they were not.
Q. None of that was before the Patent Office when it made its decision, correct?
A. Correct.
MR. LEE: Nothing further, Your Honor.
THE COURT: Ms. Mullin, anything further?
MS. MULLIN: Nothing further. Thank you, Your Honor.
THE COURT: All right. You may step down.
THE WITNESS: Thank you, Your Honor.
THE COURT: All right. Who will be your next witness?

MR. LEE: Your Honor, we're going to play now two video clips, one of Dr. Le and one of Dr. Vilcek. The first is about 15 minutes long, so maybe we could do the first and then take the recess.

THE COURT: Do the first, and then we'll take a break.

MR. LEE: All right.

THE COURT: How is that going to be charged? You going to help me out there?

MR. LEE: Yeah. 13 minutes and 17 seconds to us; 2 minutes and 16 seconds to Centocor.

THE COURT: All right. Thank you.

MR. LEE: And actually -- well, let me get a little light here. The first one is actually Dr. Knight. I misspoke. It's Dr. Knight and Dr. Vilcek. We saw Dr. Le already.

THE COURT: Okay.

MR. LEE: And the total is about 13 minutes. You can charge it all to us.

THE COURT: Oh, easy to get along with. Must not mean anything to -- okay.

Do you need to read an introduction or not?

MR. LEE: It's two minutes less, so we'll get to the break two minutes quicker.

THE COURT: Okay. Did you have any kind of introduction?

MR. LEE: Yes.

Ladies and Gentlemen of the Jury, now you will hear the testimony of Dr. David Knight, K-N-I-G-H-T. Dr. Knight is a scientist at Centocor and is one of the inventors of the '775 patent.

Dr. Knight testified at his deposition as a corporate representative on behalf of Centocor on certain topics relating to work regarding the '775 patent.

(Video playing.)

QUESTION: At any point before that project that you've just described, did you personally have any involvement in attempting to make a fully human antibody?

ANSWER: I did not.

QUESTION: To your knowledge, did anyone else at Centocor?

ANSWER: I'm not absolutely certain about that.

QUESTION: Well, in the human antibody program, was Centocor seeking to make a fully human antibody?

ANSWER: We did not characterize the

antibodies we were trying to make as fully human antibodies.

QUESTION: Why not?

ANSWER: We didn't use that term. I'm not even sure, to my recollection, that fully human was a commonly used term back then.

QUESTION: Have you ever used that term?

ANSWER: Have I ever used that term? Probably.

QUESTION: What does it mean to you?

ANSWER: To me personally, it means an antibody with -- whose amino acid sequence is very highly homologous or identical to a -- an authentic human antibody as compared to databases of authentic human antibodies.

QUESTION: Is -- okay. Let's start with you.

At any time before 1998, were you involved in making any fully human TNF-alpha antibody?

ANSWER: No.

QUESTION: And to the best of your knowledge, were any of the other named inventors involved in making any fully human anti-TNF-alpha antibody before 1998?

ANSWER: Well, there was discussion about

doing so. If the question is, was it physically constructed, my answer for myself is no. I have no knowledge of whether they were doing that or not.

QUESTION: Let's talk about the discussion you mentioned. What discussion about that subject occurred?

ANSWER: Well, as part of what I previously referred to as the human antibody program, there was often discussion about what targets ought to be considered for that program.

QUESTION: And what specifically was discussed about making a fully human anti-TNF-alpha antibody?

ANSWER: I wasn't involved in those discussions to know the details of it.

QUESTION: Were any of these --

ANSWER: I know that it was -- it was on a -- you know, on the radar screen, as were many other targets.

QUESTION: Were any of these named inventors, to the best of your knowledge, involved in any of those discussions?

ANSWER: I can't say for sure.

QUESTION: So you can't give me any examples of such discussions sitting here today; is that

right?

ANSWER: I can't give you specific examples of discussions, no.

QUESTION: So looking at this list of inventors, to the best of your knowledge, did any of these people, including yourself, come up with the idea of making a fully human anti-TNF-alpha antibody?

ANSWER: Well, I guess I would say that that was always considered to be a possibility for the program, for an anti-TNF antibody program.

QUESTION: Now, I want to focus just on this list of named inventors.

Of those named inventors, who, if anyone, came up with the idea of making a fully human anti-TNF-alpha antibody?

ANSWER: I can't tell you who specifically came up with the idea.

QUESTION: It wasn't you; is that right?

ANSWER: I recognized that that is a potential route to an anti-TNF antibody. I believe that I had had discussions with various people, again, probably 18 years ago, about what -- what a good route would be.

So the concept of us making a human anti-TNF antibody was brought forth. I don't remember

who brought it up.

QUESTION: You made a chimeric anti-TNF-alpha antibody, correct?

ANSWER: Yes. I directed that, yes.

QUESTION: So it had a murine variable region, right?

ANSWER: It did.

QUESTION: And a human constant region, right?

ANSWER: It does.

QUESTION: At what point, if ever, did you make an anti-TNF-alpha antibody that contained both a human variable region and a human constant region?

ANSWER: Well, you're -- you're assuming that I did, and you asked me this question previously.

QUESTION: And the answer is that you never did that; is that right?

ANSWER: No, that's not the answer.

QUESTION: What is the answer?

ANSWER: The answer is, I directed some work along those lines later in the 1990s.

QUESTION: After 1998, correct?

ANSWER: In 1998 or after.

QUESTION: I want to focus just on the work reflected in this patent, the '775.

At what point, if ever, before these claims were filed in the context of this project, did you make an anti-TNF-alpha antibody that had a human constant region and a human variable region?

ANSWER: Again, the timeframe being 1991?

QUESTION: Any of the work that is reflected in the '775 or '239 patent.

ANSWER: So I did not -- I did not make a human anti-TNF antibody in that timeframe.

QUESTION: And you're not aware of anyone else who did in the context of the work reflected in the '775 and '239 patents, correct?

ANSWER: That anyone that's an inventor there or anyone -- I mean, anyone in the world?

QUESTION: Anyone involved in this project in any way.

ANSWER: Not to my knowledge.

QUESTION: How long did it take to make the humanized anti-TNF-alpha antibody?

ANSWER: I don't recall specifically how long. I think I mentioned before that it took several months. That's my recollection.

QUESTION: Were you able to use known techniques in order to make the fully -- to make the humanized anti-TNF-alpha antibody?

ANSWER: Yeah. I mean, we used techniques that were readily available.

QUESTION: What is your understanding of the word inventive?

ANSWER: Well, in general, it would be having an idea that hadn't, to your knowledge, been done before and had a useful purpose.

QUESTION: And in your view, was there anything inventive about the humanized anti-TNF-alpha antibody that Ms. Trinh made?

ANSWER: Well, in my view, it was not obvious that that would work. And, again, this is -- we did this as a technology demonstration to see whether it would work, and so I think it was inventive to try that and demonstrate that one could do that with an anti-TNF antibody.

QUESTION: As of the date of that project, had you made any fully human anti-TNF-alpha antibodies?

ANSWER: Well, to the extent of my recollection about the timing of the antibody we're discussing, then the answer would be no.

QUESTION: So would you agree that as of that time, something inventive would have been required to make a fully human anti-TNF-alpha antibody?

ANSWER: I don't know. I'm trying to recall my thoughts at the time. So I would -- I guess I would say it would be not inventing new techniques but applying techniques to generate something that was inventive.

QUESTION: So do you think inventive steps would be required in actually doing that?

ANSWER: I think so.

QUESTION: Now, when you undertook this project to create a TNF-alpha antibody, did you consider using the transgenic mouse technology, the human antibody transgenic mice?

ANSWER: When we were considering how to do it was, I believe, before the technology was available to us.

QUESTION: When you were -- when you undertook the project to create the high affinity TNF-alpha antibody in the late '80s or early '90s, did you consider using phage display to do that?

ANSWER: Yes, that was an option that was considered.

QUESTION: And why did you not pursue that option?

ANSWER: Well, one reason I can think of is that we, at that time, did not have the people with

expertise in that particular technology at Centocor. There were external companies that specialized in phage display of antibodies and discovering antibodies. We -- the option was considered to make an agreement with an external phage company, and we decided not to go that route.

QUESTION: Why not?

ANSWER: Well, partly because we didn't have the expertise; partly because it would be expensive to do it with an external partner and pay not only to do it but, presumably, royalties on any product to that -- whatever the company would be.

And we felt that making a chimeric antibody could be done in-house relatively quickly and give us the kind of quality that we wanted in a therapeutic.

QUESTION: So given that you ended up paying royalties to NYU for their role in the ultimate creation of cA2, why did you choose that over the phage display approach?

ANSWER: I think we've been over this. I think it was a more rapid and predictable method. We didn't know what the final cost was going to be for any of these technologies until you actually go ahead and do it or make an agreement.

So we felt that -- that our approach was the best one, given our timing requirements and resources.

QUESTION: And at the time, you couldn't reasonably expect that making a high affinity anti-TNF-alpha antibody with phage display would be successful, correct?

ANSWER: Well, you said that. I don't think I said that.

QUESTION: Is that true, or is that not true?

ANSWER: At that -- at that time, I would say that the phage display technology was not as fully developed as hybridoma technology.

I -- and we, at Centocor, did not have internal experience with phage display, and so we couldn't say for sure how reproducible it was. It was more of an unknown to us, because we hadn't -- we didn't have the internal capabilities.

QUESTION: Had you reduced to practice the alleged invention of fully human anti-TNF-alpha antibodies at any point in time prior to 1998?

ANSWER: No. I think -- I think I've answered that question previously.

QUESTION: And did you do anything to

attempt to do that between 1991 and 1998?

ANSWER: We had -- we had no effort to make -- make them -- make those antibodies during that timeframe.

(End of video clip.)

THE COURT: Is that it?

MR. LEE: That concludes it, Your Honor.

THE COURT: Okay. Can I have the lights, please.

All right, Ladies and Gentlemen. We'll take an afternoon break. Be ready to come back in the courtroom at 3:30, 3:30.

Do not discuss the case. Have a nice break. I'll see you at 3:30.

COURT SECURITY OFFICER: All rise.

(Jury out.)

THE COURT: All right. Court's in recess until 3:30. I'd like to see counsel at the bench. Court's in recess.

(Bench conference.)

THE COURT: All right. What's y'all's best guess timing-wise? I want to try to tell the jury something this afternoon, I believe, if we're going to get through early tomorrow. The way we're going, you know, I want to know if I need to stay here till 5:30

today.

MR. LEE: We have one additional clip to show. It's about 15 minutes, and then we're going to put Mr. Slottje on, about 45, 50 minutes on direct, he's the damage guy, and then we'll rest.

THE COURT: After his cross-examination.

MR. LEE: After his cross-examination.

THE COURT: Well, we might be able to finish that, and then we'll start rebuttal maybe.

How long -- how much time are you going to need for rebuttal?

MS. ELDERKIN: We have one videotape. It's about 10 minutes. And we'll have at least Dr. Adams for maybe half an hour, maximum. And we haven't decided if there's going to be -- we're going to talk about it at the break.

THE COURT: Well, let me tell you, you've got three and a half hours.

MS. ELDERKIN: Right. We certainly won't use three and a half hours, Your Honor. I would expect we would be through in the morning.

THE COURT: You think you'll probably be resting late this afternoon?

MR. LEE: Yeah, I think so, Your Honor.

THE COURT: All right.

MS. ELDERKIN: I'm not sure I --

THE COURT: Well, I'm going to tell them that maybe we'll -- I'll tell them -- it's always better if I tell them something, that maybe I'll let them go by 2:30 tomorrow, and then if we get through at noon tomorrow, well, they'll be happy with all of us.

I'm not running for reelection. I wouldn't get far. So, anyway, I like to at least not put y'all in a bad light, is what I'm trying not to do. Because if I tell them noon and then we keep them till 3:00, they're going to be mad at y'all, not me.

MR. LEE: Right. Right.

MS. ELDERKIN: No way we'll go past that.

THE COURT: So I'll tell them 2:30 tomorrow, 3:00, something like that.

Okay. All right.

MS. MULLIN: Thank you, Your Honor.

(Bench conference concluded.)

(Recess.)

COURT SECURITY OFFICER: All rise.

(Jury in.)

THE COURT: Please be seated.

All right. Deposition.

MR. LEE: Last deposition, Your Honor.

It's Dr. Vilcek, and you can charge the

time to us.

THE COURT: Okay. What's the total?

MR. LEE: Total of 11 minutes and 40 seconds.

THE COURT: Okay.

MR. LEE: Ladies and Gentlemen, the next video clip will be the testimony of Dr. Jan Vilcek, V-I-L -- I'm sorry -- V-I-L-C-E-K. Dr. Vilcek is a scientist at New York University and is one of the inventors on the '775 patent.

Dr. Vilcek testified at his deposition as a corporate representative for New York University on certain topics relating to the '775 patent.

(Video playing.)

QUESTION: Does the 1991 -- the March of 1991 application tell us how to make a human anti-TNF-alpha antibody?

ANSWER: I don't recall that it would specifically do that. No.

QUESTION: You have the March of 1991 application before you. That's DX7. Can you turn, please, to Page 9 of the application? It's marked Page 9 on the bottom center.

I want to direct your attention to Line 5. The first sentence in that paragraph reads:

The development of human mABs that could circumvent the above problems has encountered a number of obstacles.

Do you see that?

ANSWER: Yes.

QUESTION: And did you review that statement before this application was filed?

ANSWER: I don't remember. No.

QUESTION: Was that a true statement as of March 18th of 1991?

ANSWER: I think so. Yes.

QUESTION: Now, the next sentence says: Because human spleen cell donors are rare, human mAB-producing cell lines are typically obtained from human peripheral B-cells immortalized by infection with Epstein-Barr virus, EBV.

Was that a true statement as of March 18th, 1991?

ANSWER: Yes, I believe so.

QUESTION: The next two sentences say: Such cells may not be useful for scale-up and production of human pharmaceuticals. Furthermore, the presence of human viral genetic information in such EBV immortalized human antibody-producing cell lines may be a barrier to their safe use.

Were those true statements as of March

18th of 1991?

ANSWER: That, I think, was the prevailing opinion, so, yes, they were correct.

QUESTION: Now, the next two sentences say: In addition, since human TNF has evolved in the face of the human immune response, key antigenic epitopes may not be recognized by the human immune system. Such antigens would not be expected to elicit useful immune responses in man.

Were those statements accurate as of March 18th, 1991?

ANSWER: Well, these were -- these -- these statements, I think, summarized, again, the prevailing view at that time. The -- the first sentence says: Key antigenic epitopes may not be recognized. They don't say they are never recognized.

QUESTION: Now, you would agree that this paragraph describes obstacles in creating human antibodies, correct?

ANSWER: Well, some of the obstacles. Yes.

QUESTION: Were there others that aren't referenced here?

ANSWER: Probably.

QUESTION: What were they?

ANSWER: Well, again, I -- I don't recall, but I'm sure that this is not an exhaustive listing of all the problems.

QUESTION: Does this application tell us how to overcome those problems in developing human antibodies?

ANSWER: As I said, I have not reviewed the whole application very carefully, so I'm not sure.

QUESTION: Well, just based on your own understanding as of March of 1991, had you come up with a way to overcome those problems?

ANSWER: No. I did not.

QUESTION: And to the best of your knowledge, had any of the other named inventors on the '775 and '239 patents come up with a way to solve those problems as of March, 1991?

ANSWER: I don't know.

QUESTION: Not to your knowledge?

ANSWER: Not to my knowledge.

QUESTION: And was there ever a point before the '775 patent application was filed in July of 2002, when you had come up with a way to overcome those problems?

ANSWER: I don't recall, and I believe that -- no, I did not come up with a way to -- ways to

overcome these -- these obstacles.

QUESTION: And to the best of your knowledge, had any of the other named inventors on the '775 and '239 patents come up with a way to overcome these obstacles at any time before July 18th of 2002?

ANSWER: I don't know, but I'm not aware of such efforts.

QUESTION: So not to your knowledge, correct?

ANSWER: Yes.

QUESTION: So I'm going to have this document marked as Exhibit 112.

This is an article by Achim Moller and others.

ANSWER: Right.

QUESTION: -- headed, Monoclonal Antibodies to Human Tumor Necrosis Factor-Alpha In Vitro and In Vivo Application.

Do you see that?

ANSWER: Yes.

QUESTION: And this article is dated 1990. Do you see that?

ANSWER: Yes.

QUESTION: And if you turn to the second page of this article, if you -- do you see in the first

line there's a reference to mAB 195?

ANSWER: Right.

QUESTION: Have you reviewed this article before?

ANSWER: So until -- if you had asked me two days ago do I know anything about monoclonal antibody 195, or mAB 195, I would have said, no, that doesn't mean anything.

And we reviewed this with counsel, and what I do recall -- and, you know, this is my memory, independent of -- of the information that we reviewed with counsel -- that I knew about Achim Moller's antibody. And at one time I looked at this article and found the information of some interest.

So that's the -- and I -- I did remember it, because I remembered that they tested some properties of the antibodies and they -- they were of some interest.

QUESTION: I'm going to put before you what's been previously marked as Defendants' Exhibit 28.

Let me know when you've had a chance to look at that.

ANSWER: Okay.

QUESTION: Now, this is a letter from you to Scott Siegel dated August 15th of 1990, correct?

ANSWER: Yes.

QUESTION: And this letter was written before the priority application for the '775 and the '239 patents was filed in March of 1991, correct?

ANSWER: Yes.

QUESTION: If you turn to the second page, that's your signature, correct?

ANSWER: Yes.

QUESTION: And Peter Dadonna and Junming Le are copied on this letter, correct?

ANSWER: Yes.

QUESTION: And those are two other named inventors on the patents that are being asserted in this case, correct?

ANSWER: Yes.

QUESTION: Now, turning your attention to the first page of the letter, third paragraph, the first sentence, and it straddles over onto the next page, reads: Based on our demonstration that mAB A2 neutralized chimp TNF, but failed to neutralize TNF produced in adherent cells of cynomolgus, rhesus, or baboons, it appears that mAB A2 resembles an antibody described by Moller, et al, parenthesis, cytokine 2, 162 to 169, 1990, a copy of which I sent you about two weeks ago.

Do you see that?

ANSWER: Yes.

QUESTION: And you're referring back to the letter we just looked at, correct?

ANSWER: Yes.

QUESTION: And that -- that also refers to the Moller article that we looked at, which is Exhibit -- Defendant 112, correct?

ANSWER: Yes.

QUESTION: Why were you bringing this to the attention of Dr. Siegel and Dr. Dadonna and Dr. Le?

ANSWER: I thought it was interesting.

QUESTION: Why is that?

ANSWER: Because, as I said, the -- the neutralization of TNF produced in different animal species by the Moller antibody was similar to what we found for A2.

QUESTION: The next sentence says: Do you think it would be worthwhile to request a sample of the antibody described by Moller, et al, in order to compare it side-by-side with mAB A2?

Do you see that?

ANSWER: Yes.

QUESTION: Did anyone respond to that question?

ANSWER: I have no recollection of seeing a response.

QUESTION: Did you ever request the Moller antibody?

ANSWER: I don't remember that I would have requested it, and I think I probably would remember if I did. But I can only say I have no recollection of requesting it.

QUESTION: Was any testing done by NYU of the Moller antibody?

And I'm talking about MAK195, in case it's unclear.

ANSWER: There is no record or information that NYU would have done any testing -- that -- that I am aware of.

(End of video clip.)

MR. LEE: Your Honor, Ms. Wigmore will present our next witness.

THE COURT: Who will be -- who will it be?

MS. WIGMORE: Daniel Slottje.

THE COURT: Come around.

COURTROOM DEPUTY: Raise your right hand.

(Witness sworn.)

DANIEL SLOTTJE, Ph.D., DEFENDANTS' WITNESS, SWORN

DIRECT EXAMINATION

BY MS. WIGMORE:

Q. Good afternoon, Mr. Slottje.

A. Good afternoon.

Q. Would you please introduce yourself.

A. My name is Daniel Slottje.

Q. Where do you live?

A. I live in Dallas, Texas.

Q. And where do you work?

A. I actually have two jobs. I'm a professor of economics at Southern Methodist University in Dallas, and I work for a consulting firm called FTI Consulting.

Q. What types of services does FTI provide?

A. We do financial management and litigation support consulting.

Q. Would you please describe your educational background?

A. Sure. I have a Master's -- I have a Bachelor's degree in economics from Clemson University and a Ph.D. in economics from Texas A&M University.

Q. Have you --

A. And my voice was fine, but I seem to have lost it, so I think I'll just grab a little water here. I'm sorry.

Q. Take your time.

Have you published in your field, Dr. Slottje?

A. Yes, I have.

Q. And approximately, how many publications do you have?

A. I've published 150 articles and books.

Q. What do those publications address generally?

A. Generally, they deal with different economics and econometric issues, including intellectual property, law and economics, and microeconomics.

Q. Do you have any previous experience in calculating damages in a patent case?

A. Yes, I have.

Q. Can you describe to us the breadth of your experience in that area?

A. I've been doing damages in patent cases since at least 1991.

Q. Now, you've told us that you're also a professor at SMU.

A. Yes.

Q. What types of classes have you taught?

A. I've taught courses in law economics, econometrics, and microeconomics.

Q. For how long have you been a professor at SMU?

A. For 25 years.

Q. Now, I would like to pull up what's been

marked and preadmitted as DX467. It's also Tab 1 in your binder, if you prefer a hard copy.

Could you identify that for us, please?

A. It's called my academic CV or curriculum CV.

Q. What do you mean by your academic CV?

A. It lists the publications that I just mentioned, the books and articles that I've written, as well as my academic positions.

Q. Now, do you also have a professional CV for your consulting work?

A. Yes.

MS. WIGMORE: And if we could pull up DX853, which is also preadmitted.

Q. (By Ms. Wigmore) Could you identify this for us, please, Professor Slottje?

A. That is a record of my professional experience as a consultant.

Q. Taken together, are DX467 and DX853 accurate and complete summaries of your professional experience?

A. Yes.

Q. Professor Slottje, have you been retained as an expert in this case?

A. Yes, I have.

Q. By which party?

A. By Abbott.

Q. Are you charging for your time spent on working on this case?

A. Yes, I am.

Q. Is any -- is any portion of your compensation dependent on your opinions or the outcome of this case?

A. No.

Q. Did anyone from FTI assist you in your work on this matter?

A. Yes.

Q. Approximately how many people?

A. Six people.

Q. Now, what were you asked to do in this case?

A. I had two primary tasks. I was asked to look at the analysis that was done by the opposing expert, and I was asked to arrive at my own independent economic damage analysis.

Q. Now, you mentioned you were asked to analyze the opinions of the opposing expert.

Are you referring to Dr. Gering who testified here yesterday?

A. Yes.

Q. What materials did you consider in performing those tasks?

A. I looked at Dr. Gering's expert report and the underlying documents that he provided in support of his

report.

I also looked at hundreds of thousands, or my team, of pages from the case. I looked at independent, third-party information about the market.

I read various depositions in the case. I also talked to various individuals at Abbott.

Q. Dr. Gering showed us a slide yesterday about some various types of information he considered.

Did you consider similar materials in your work on this case?

A. Yes, I did.

Q. Now, have you been in the courtroom for the testimony that's been provided so far in this case?

A. Yes, I have.

Q. And you were here for the testimony of Dr. Gering yesterday?

A. Yes.

Q. You mentioned that one of your tasks was to evaluate damages.

Did you apply any assumptions in making that analysis?

A. Yes, I did.

Q. What were those assumptions?

A. I assumed that the patents were valid and infringed.

Q. Have you formed any opinions on your own with respect to the issue of infringement or the issue of validity?

A. No, I have not.

Q. You've just assumed that the patent's valid and infringed in order to assess the damages issue; is that right?

A. That's correct.

Q. Now, were you here when Dr. Gering testified that Centocor and NYU should receive over a billion dollars in lost profits?

A. Yes.

Q. Do you agree with Dr. Gering?

A. No, I don't.

Q. Did you conduct your own analysis of what lost profits, if any, should be awarded, if the '775 patent is valid and infringed?

A. Yes, I have.

Q. We'll come back to the details shortly, but could you just briefly summarize for us your general opinion as to what, if any, lost profits should be recovered, if the '775 patent is valid and infringed?

A. If lost profits are awarded, it's my opinion they should only be awarded on the Crohn's disease indication and only up through April of 2008.

Q. Now, in what areas did Dr. Gering suggest that lost profits should be awarded?

A. He suggested there's -- you heard discussions previously about three major areas. Crohn's is part of gastroenterology. You also heard him talk about rheumatology and dermatology.

I don't believe it's appropriate to award lost profits in either rheumatology or dermatology.

Q. And we'll come back in a moment to the reasons for your opinion.

But were you also here when Dr. Gering gave the opinion that Centocor and NYU should get an additional $1 billion in damages in the form of a reasonable royalty at a 15-percent rate?

A. Yes.

Q. Do you agree with Dr. Gering's opinion concerning damages in the form of a reasonable royalty?

A. No, I don't.

Q. Could you briefly summarize for us your opinion concerning a reasonable royalty that would be appropriate, if the '775 patent is valid and infringed?

A. My opinion, a reasonable royalty would be 2.25 percent on U.S. sales, and 1.25 percent on sales outside the United States.

Q. Now, let's turn to the details of the opinions

you've just summarized for us, starting with lost profits.

We heard Dr. Gering describe yesterday a four-factor test for assessing lost profits. He referred to it as the Panduit Test.

Do you recall that?

A. Yes.

Q. Did you apply the same four Panduit Factors in your damages analysis?

A. Yes, I did.

Q. And did you consider each of those four factors in reaching your conclusion?

A. I went through every one of them one by one.

Q. Could you just describe for us generally your understanding of the purpose of the lost profits analysis?

A. My understanding of going through a lost profits analysis and going through those four factors is determining whether the party that has had their product allegedly infringed, had the infringement not occurred, would they have actually made sales.

And you go through those four factors to determine if it's appropriate to award lost profits based on every one of those. And if any one of those you fail, my understanding is then you're not awarded

lost profits.

Q. And you referred to a party who's had a product infringed. Do you mean had its patent infringed?

A. Yes.

Q. Now, we've heard testimony about the but-for world.

Can you remind us what a but-for world is?

A. In undergoing that exercise where you're trying to figure out what the but-for -- what would happen -- it's kind of a complicated process.

If you're going to go back and suggest but for the infringement the -- the party that owns the patent, in this case Centocor, and the product that we're talking about, specifically here is Remicade, whether there had been more sales of Remicade but for the alleged infringement of -- by Abbott, and specifically Humira.

So what we have to do is be able to go back in time and try to figure out what would the market have looked like back in 2006 specifically, or 2007. But with respect to what the market would have looked like, if the amount of Humira that's alleged to have been infringed, is taken off the market.

It's kind of a complicated thing to do,

because you have to go back and figure out a number of things. But that's really -- the but-for world means, what does the market look like but for the fact that Humira, that is alleged to be infringed, has to be taken off.

Q. So you assume that the infringing product, if you're assuming that's Humira, is not in the market and assess what would have happened to the sales that Humira had; is that right?

A. Yes.

Q. Now, you testified earlier that you disagreed with Dr. Gering's lost profits analysis.

Did you work with us in preparing some slides to assist you in explaining your opinions?

A. Yes, I did.

Q. If you could turn to the first slide, which is DDX52.

Could you please identify your three main areas of disagreement with Dr. Gering?

A. The first -- the first bullet point there, what I'm trying to say there is, again, when we're talking about for this but-for world, licensed Humira is a valid, non-infringing alternative.

And it's a little confusing, because, again, we're going back and we're taking the infringed -- the

allegedly infringed Humira off the market and we're trying to figure out what those patients would have done, we have to recall that there is still licensed Humira that's available to them.

And that's the first thing that I believe that Dr. Gering failed to do, is he failed to account for the fact that licensed Humira would have been available in the but-for world as a non-infringing alternative.

Q. And we'll come back to that one in more detail, but what was your second main area of disagreement?

A. I also believe that there are differences in the products. You've heard a lot of discussion about that the last couple of days, and that these differences in the products have implications for different market segments as well.

And just by -- just like in the but-for world, you have to take into account the fact that there may be non-infringing alternatives.

You also have to take into account, if these products are different, then it may not necessarily follow that Remicade would have automatically made more sales, if they're not in the same market segment and they're perceived by some consumers, patients, and doctors as being different products.

Q. What is your third main area of disagreement with Dr. Gering concerning lost profits?

A. I also don't believe that Dr. Gering took into account the fact that by virtue of the fact that Humira was on the market in 2006. You also have heard a significant amount of evidence and testimony talking about the market growing.

So if you're going to go back and figure out again what -- how many lost sales and how many lost profits Remicade would have had, you have to take into account, if Humira helped grow the market, you've got to adjust back for the fact that they wouldn't have been there to grow the market.

And those are the three main areas.

Q. Now, let's go in a little bit more detail, starting with the first area.

What is a non-infringing alternative?

A. A non-infringing alternative would have been a particular drug that would have, back in the but-for world -- again, if you think about it, that all of the patients that were taking infringing Humira and are no longer allowed to do that, what choices would they have had, if infringing Humira was not on the market.

Non-infringing means what choices would they have had that would not have infringed Centocor's

patent.

Q. And are there other choices on the market besides Remicade in the various categories that you've mentioned?

A. Yes.

Q. And you're suggesting that licensed Humira should have been considered as one of those; is that correct?

A. That's what I believe, yes.

Q. Now, we've been talking about licensed Humira, and there was a bit of testimony yesterday about that, but I want to make sure that we understand what you're referring to.

What activities, with respect to Humira, are licensed?

A. My understanding is that when Humira is taken in combination with Methotrexate -- and you've also heard that referred to as being co-administered -- that that is what we're calling licensed Humira.

Q. Are you familiar with the term monotherapy?

A. Yes.

Q. How is the term monotherapy used in relation to Humira?

A. Again, my understanding is that if Humira is taken by itself and it's not taken with another drug,

specifically here, not with Methotrexate, then that's called monotherapy.

Q. And is that licensed or not licensed?

A. It's not.

Q. Turning to the next slide, which is DDX53, can you just summarize for us what the license means with respect to Humira in the but-for world?

A. Again, when we're going back and we're trying to determine what the world would have looked like if there had been no alleged infringement, we have to take not licensed, or monotherapy Humira, out of the equation. We have to take that off the market and figure out what those patients would have done, if that wasn't there.

But licensed Humira still would be -- still would be there.

Q. Now, we heard some testimony yesterday about arbitrator rulings.

Is it your understanding that this license was determined by an arbitrator?

A. Yes.

Q. And that the scope of the license was also decided by an arbitrator; is that right?

A. That's my understanding.

Q. Did the arbitrator address any issues with

respect to the validity or infringement of the '775 patent?

A. It's my understanding it did not.

Q. That's an issue that the ladies and gentlemen of the jury will be deciding; is that correct?

A. That's right.

Q. Now, have you reviewed the arbitration awards?

A. Yes.

Q. And you have an understanding of the license and its scope?

A. Yes.

Q. Now, if we could turn to the next slide, how should licensed Humira be considered in the lost profits analysis?

A. Licensed Humira should be considered again, as we just mentioned, as a viable, available, non-infringing alternative in our but-for world.

Q. And in terms of the first item here, excluding it from the damages base, what does that refer to?

A. I'm sorry.

What that means is that when you're trying to determine what the damage base is, you have to subtract out the licensed Humira, because it's not going to be subject to damages.

Q. So the first step is to take it out of the

damages base so that there will be no damages on licensed sales; is that correct?

A. Yes.

Q. And what is the next step?

A. The next step is to take into account as a non-infringing alternative, that I just mentioned.

Q. Now, you mentioned that you and Dr. Gering have a disagreement with respect to licensed Humira. You mentioned that you have excluded it from the damages base.

Has Dr. Gering done the same thing?

A. Yes, he has.

Q. So if we turn to the next slide, that shows that you've both accounted for that in the damages base.

So what is your disagreement with Dr. Gering concerning licensed Humira?

A. Again, when we go back in time to 2006 and we're trying to figure out what those patients are going to do and they are no longer able to take the infringing Humira, my belief is that those patients have the choice of taking Humira with Methotrexate.

In Dr. Gering's analysis, he did not take into account the fact that non-infringing alternative or licensed Humira would still be available. So we disagree about that.

Q. So if we could turn to the next slide.

There's a difference between the two of you in terms of addressing Humira as a non-infringing alternative.

A. Correct.

Q. Dr. Gering testified that he did take into account licensed Humira by excluding it from the damages base.

Is that enough?

A. That accounts for taking it out of the base that he's going to start to calculate his damages on, but that doesn't take into account the fact that when we have to figure out what these patients would do in our but-for world, that the licensed Humira is still available.

So it's kind of complicated, because he subtracted it out of the base that he's going to calculate his lost profits on. He does that right. But then he doesn't take into account the fact that in our but-for world that still is a viable or reasonable non-infringing alternative available to -- thinking of those people that were -- that were on Humira, taking it by itself, or as monotherapy.

Q. We heard testimony from Dr. Gering about reallocating market share in the but-for world.

What does that mean?

A. My understanding of what Dr. Gering did is he looked at what the world actually looked like. He would look -- let's -- you've heard discussions about Enbrel -- there's another drug called Enbrel.

He looked basically at shares of the various drugs, what they actually were, but it's important to remember what they actually were with all Humira in the market.

And then he said, now let's pretend that we take infringing Humira away, and then let's take those same market shares that actually existed when all Humira was still there, and we'll reallocate adjusting for those.

He also does take out -- he takes out something called Remicade failures. So he does do an adjustment. But he doesn't do the adjustment that we're talking about here, accounting for the fact that there still is a viable, non-infringing alternative left, which is licensed Humira.

Q. And what portion of the market did Dr. Gering reallocate to licensed Humira in his analysis?

A. None.

Q. What effect did that have on his lost profits analysis?

A. Well, once again, if you think about it, if he is assuming that all of those -- all of the sales of the infringing Humira are simply going to go to the parties that are left and he doesn't take into account the fact that some of those -- we'll call them monotherapy or infringing Humira sales -- would have gone to non-infringing Humira, then he's overstating his damage numbers.

Q. Let's turn to the second main difference that you had with Dr. Gering, and that related to differences in products in the market segments.

If you could turn to Slide DX57 -- DDX57.

Could you explain for us, please, your opinion concerning the differences between Humira and Remicade that Dr. Gering had failed to consider?

A. Once again, you've heard a lot of discussion over the last couple of days talking about the fact that these products, Humira and Remicade, have differences. They're different types of antibodies.

You've heard discussions that Humira is basically what's called a fully human antibody. You've heard discussions that Remicade is what's called a chimeric antibody.

And there are other implications with respect to patients' perceptions of things based on the fact

that they are different types of antibodies.

Q. Now, you mentioned implications in terms of patient perceptions.

Have you reviewed materials addressing perceptions of safety as between Remicade and Humira?

A. Yes.

Q. And we saw many of those yesterday, and I don't intend to go through all of the exhibits again.

But what impact did those exhibits addressing perceptions of safety as between Humira and Remicade have on your lost profits analysis?

A. Once again, they just suggest that there may be differences in the -- in the perception of consumers and how they view -- how they view the products.

Some may view them as different products, and that has certain implications for how we divide up things in that but-for world again.

Q. Now, you're familiar with a product known as Simponi?

A. Yes.

Q. And that's also known as golimumab?

A. Yes.

Q. Can you remind us, please, what is Simponi or golimumab?

A. My understanding is that's a product that's

been approved recently that's also produced by Centocor that is a fully human antibody that also gets injected.

Q. And what impact, if any, did that have on your analysis of the market for lost profits purposes?

A. Well, once again, it's more -- it's more data that I've seen that suggest that individuals in these -- that use these drugs to distinguish between them.

Q. So if a patient is taking a human antibody and we're assessing that patient's preferences in the but-for world, should that be considered the type of antibody they're currently taking?

A. Yes.

Q. Now, turning to the next slide, you mentioned -- let's move back; the next bullet on actually the prior slide.

The next difference that you mentioned was the modes of administration.

A. Yes.

Q. We've heard a lot of testimony about that, so I don't intend to go through all of those documents again.

But could you just describe for us generally what is the difference between Remicade and Humira with respect to this issue?

A. You've heard that Remicade is infused, and

Humira is injected. And I know you've heard that and heard that, so...

Q. And what impact does that have on the lost profit analysis?

A. Well, it can have an important impact, because the fact that people that use -- that have a preference for an injection in this but-for world that were on Humira.

So we know that they actually already showed they have a preference for an injected drug. It doesn't follow that they might not want to go to an infused drug.

Q. And the last difference that you identified here is differences in FDA approval.

What does that refer to?

A. We also heard a lot of discussion about the fact that different drugs for different indications have different approvals, such as -- as a simple example, you heard that Remicade, when you're talking about rheumatology, specifically RA, has to be administered the way the FDA approves it, used in conjunction or combination with Methotrexate, whereas Humira can be administered either with or without Methotrexate.

So depending on which indication you are talking about, what therapy you're talking about, that

has -- that has implications for FDA approval.

Once again, in our but-for world, when we're trying to figure out what's going to happen to those Humira-infringed sales, that's something else that we should take into account.

Q. Now, did Dr. Gering take into account any of these three main differences between Humira and Remicade in constructing his but-for world?

A. No.

Q. And he mentioned that he reallocated market share.

Why did that not account for these differences?

A. Because, again, as we talked about a few minutes ago, because you look at what actually happened in the world, if you know what the market shares look like, when all Humira is there, meaning that all the Humira users that we know are patients that were taking -- who liked getting an injection or chose to get an injection, who chose to use monotherapy Humira, and then we have to decide and figure out and imagine what's going to happen in our but-for world, where will those patients go?

What choices would those patients make?

And if those patients have strong preferences

as well as the fact that they know that certain other drugs, Humira with Methotrexate, is available, is it likely that they would switch to another biologic, Remicade, which also has to be used with Methotrexate.

So all of these things together make it very problematic to try to figure out what exactly would happen in this but-for world. If we can't figure that out, if we have to guess, you don't get lost profits.

Q. This is all quite theoretical. So why don't we walk through some examples and see the implications.

First of all, you've been talking about market segments and approvals. How is the biologics market divided in terms of diseases or disease categories?

If you would turn to the next slide.

A. Once again, you've heard discussion about this. It's divided between rheumatology, dermatology, and gastroenterology.

Q. And what I would like to do is to just take some examples within those categories, starting with rheumatology.

Now, what is the biggest indication in the rheumatology market segment?

A. Rheumatoid -- rheumatoid arthritis.

Q. If we could turn to the next slide.

Now, what -- we heard Dr. Bazemore testify

yesterday about the various product approvals and choices, and we won't go over all of that again, but if you could describe for us generally what options are available to a patient who wants to take a biologic for rheumatoid arthritis, if Humira monotherapy is not on the market.

A. Depending on the time period, what this indicates is the patient that was taking mono -- monotherapy Humira was trying to decide where to go to next -- Enbrel, Remicade, Kineret, licensed Humira, Orencia, Rituxan, and then later on, Simponi and Cimzia -- would have been available.

Q. Now, Simponi and Cimzia were just very recently approved; is that correct?

A. Yes.

Q. So did you consider those as part of your lost profits analysis?

A. Well, I considered them in the sense that there -- this is just an example to you. Obviously, depending on the timeframe, those little circles might not be there, but, yes, I took them into account.

Q. So the market varies over time and the choices available might vary over time?

A. Yes.

Q. Now, let's take an example, if we could turn

to the next slide.

You mentioned that the mode of administration is an important difference between Humira and Remicade.

If a patient is taking Humira monotherapy in the existing world and that choice is no longer available, what options would that patient have, if he or she wants to still take an injectable as opposed to an IV therapy?

A. Enbrel, Kineret, licensed Humira, Simponi and Cimzia, and that's why those are in yellow, to show that those are choices. If a patient that prefers to have the drug injected, those would be choices they would have back in our but-for world.

Q. Now, did Dr. Gering take those choices into account when he did his lost profits analysis for rheumatology?

A. No.

Q. What did he do instead?

A. He -- as we've already discussed, he basically mechanically divided up the market, based on what actual market shares were as of the time of the actual time with Humira in the market.

Q. He did not consider a patient's potential preference for an injectable alternative?

A. No.

Q. Now, if we could turn to the next slide.

You've talked about Methotrexate and the difference and approval between Remicade and Humira.

Let's take another example.

If a patient is taking Humira monotherapy in the existing world but wants to continue to take a therapy without Methotrexate, what options would he or she have in the but-for world?

A. Enbrel, Kineret, Orencia, and Cimzia.

Q. Would Remicade be an option?

A. No.

Q. And just going back to the past slide -- the previous slide for one moment.

If that patient who wants an injectable alternative has to choose, would Remicade be an option for that patient?

A. No.

Q. Okay. Turning back to the Methotrexate slide.

In terms of Methotrexate, we heard testimony from Mr. Bazemore about the side effects of Methotrexate.

Are you familiar with that?

A. Yes.

Q. And how does that bear on the patient preferences in this market?

A. Well, the whole point is that it may have an effect. And if we don't know what the overall effect is, then it's something that we need to take into account, because it can impact how we reallocate or adjust what's going to happen in our but-for world. And it's something that bothers some patients.

Q. You heard some testimony from Dr. Gering about off-label sales.

Do you recall that?

A. Yes.

Q. What is an off-label sale?

A. My understanding is an off-label sale means that you can take a drug -- a doctor can prescribe a drug to you, even though it's not approved by the FDI (sic) for that particular use. He can still -- he or she can still do that.

Q. Now, is it legal for a company to market a product for an off-label purpose?

A. No.

Q. How did Dr. Gering take off-label sales into account in his lost profits analysis?

A. He assumed that a significant number of patients that were taking monotherapy Humira would have taken Remicade off-label.

Q. Did he provide any basis for that assumption?

A. No.

Q. Let's turn to the next slide.

Now what if a patient who's currently taking Humira wants to take both an injectable therapy and a therapy without Methotrexate in the but-for world?

A. That patient would face choices of Enbrel, Kineret, and Cimzia.

Q. Would Remicade be a option for that patient?

A. No.

Q. Again, did Dr. Gering consider any of these differences when he constructed his but-for world for lost profits?

A. He did not take them into account in his ultimate calculations.

Q. We've talked about the rheumatology area. Now let's spend just a little bit of time on dermatology.

Are there any differences between Remicade and Humira in terms of their approvals for psoriasis, which is the biggest indication in the dermatology market?

A. My recollection is that Humira is approved by the FDA for moderate to severe psoriasis, whereas I believe that Remicade is approved for severe psoriasis.

Q. And we've heard about the difference between the IV administration and the injectable.

What, if any, significance does that have in

the dermatology market segment specifically?

A. Well, you've heard discussion about that, too. Dermatologists don't like to mess around with that thing over there. They don't like giving people IVs in their offices. They don't like having the crash cart that they have to have.

And it has an effect, then, on the physician's preferences with respect to using IVs.

Q. Now, turning to Slide 63, what options are available today for a biologic in the psoriasis market?

A. Today?

Q. Yes.

A. Is it Amevive?

During the entire time period -- I can't say that one -- but I think it's Amevive, Raptiva, Enbrel, Remicade, and licensed Humira.

Q. Now, is Raptiva still available on the market?

A. No.

Q. Was it available during any portion of the damages period?

A. Most of this damage period that we're talking about it, it was available, but it's not right now.

Q. Let's take another example, turning to Slide 64.

If a patient is taking Humira monotherapy for

psoriasis and wants to continue with an injectable alternative, what options would he or she have in the but-for world?

A. If we're talking about back in 2006 and 2007, Raptiva, Enbrel, and licensed Humira, again, licensed Humira.

Q. And at some point, Raptiva became unavailable; is that right?

A. Yes.

Q. Would Remicade be an option for that patient?

A. No.

MS. WIGMORE: Let's turn to the next slide.

Q. (By Ms. Wigmore) Now, you mentioned the difference in approval between Remicade and Humira in terms of moderate psoriasis. And specifically, you mentioned that only Humira is approved for moderate.

Do you recall that testimony?

A. Yes.

Q. Let's assume a patient is taking Humira monotherapy for moderate psoriasis in the existing world and wants to continue with an approved therapy for moderate psoriasis in the but-for world.

What options would that patient have?

A. Amevive, Raptiva earlier on, Enbrel, and

licensed Humira.

Q. And did Dr. Gering consider those preferences and what impact they would have on the market?

A. No.

Q. All right.

MS. WIGMORE: Let's turn to the next slide.

Q. (By Mr. Wigmore) This just shows if a patient wants both, an injectable and an approved alternative for moderate therapy (sic), what options would be available in the but-for world?

A. Raptiva, Enbrel, and licensed Humira.

Q. Would Remicade be an option?

A. No.

Q. Now let's spend a few moments on the gastroenterology market, which is the third of the market segments that we've been discussing.

If we could turn to the next slide.

Now what options were available on the market for Crohn's disease at various points in time during the damages period?

A. Remicade, a very limited amount of licensed Humira, a drug called -- I can't say that.

Q. Tysabri?

A. That one. Tysabri and Cimzia.

Q. Okay. You mentioned a limited amount of licensed Humira.

Why do you see that?

A. Because it wasn't used very much with Methotrexate to treat Crohn's disease.

Q. So did you consider licensed Humira as an alternative in the but-for world for the Crohn's disease indication?

A. I did not in my ultimate analysis.

Q. Let's turn to now to Tysabri.

Did you consider that as a non-infringing alternative in your but-for world for Crohn's disease?

A. No, because it's a really nasty drug, and it does nasty things to people. I did not.

Q. So if a patient is taking --

A. That's my understanding. I don't want to get sued by them.

Q. If a patient's taking Humira monotherapy today and wants to continue with a biologic, what options would that patient have in the but-for world?

A. In the but-for world, those patients would have been -- depending on the time, they would have had either Remicade for much of the period, and that would have been it, or they would have had Cimzia later on after April of 2008.

Q. Now, you mentioned that Cimzia launched in April of 2008.

What type of biologic is Cimzia in terms of its mode of administration?

A. Cimzia is also an injectable drug.

Q. As opposed to Remicade which is an IV drug?

A. Yes.

Q. Now, how does that, the launch of Cimzia, bear on the lost profits analysis for Crohn's disease and gastroenterology?

A. The reason it bears on it and the reason that all of these different things we're talking about are important is because my job is to try to figure out where those infringed or monotherapy Humira sales are going to go.

And if I can't do that, if I don't have the data or the information to do that without guessing, then I say I can't do it without guessing, and then you don't get lost profits.

You still get a reasonable royalty on those sales, but it's not appropriate to give somebody lost profits if we're not sure how that market would -- what that market would look like, where those sales would go in the but-for world.

So at least from -- if we're talking about

July of 2006 through April of 2008, the only choice those folks would have had is to go from monotherapy Humira to Remicade.

So I think it is reasonable to give them lost profits on those Remicade sales, because they didn't have any choice.

But after April of 2008, Cimzia is a viable, non-infringing alternative. It happens to also be an injectable drug. So just from a common-sense perspective, people that are taking -- currently taking Humira, which is injectable, can now take Cimzia, which is injectable.

MS. WIGMORE: Well, let's turn to the next slide.

Q. (By Ms. Wigmore) And we talked about licensed Humira not being used in this market, so let's move on to DX70.

MS. WIGMORE: Let's move back. I'm sorry. We don't have the right slide. Let's go back to the one on the gastroenterology market.

Q. (By Ms. Wigmore) So explain for us, please, how did the availability of these alternatives bear on your opinions concerning lost profits and what did you conclude?

A. Well, I concluded in that every one of these

indications of therapeutic groups, that there's a segmented market, and it's just not clear where those Humira sales would have gone, that I can't determine that without guessing, so only in Crohn's disease do I believe it would be appropriate to award lost profits.

Q. Now, you mentioned that Dr. Gering did not adequately consider these other available alternatives in his but-for world.

Would it be possible in the rheumatology and dermatology segments to create a but-for world that did adequately account for them?

A. You don't have the data to do it. If you don't have the data to do it, then it's not -- I don't believe it's appropriate to do it, because you would have to guess.

Q. Now, turning back to our original slide, DX52, we talked about some main differences with Dr. Gering, and we've walked through the first two.

Can you describe for us, please, the third area of disagreement which relates to market growth?

A. Market growth is what I was talking about a little earlier. You've all heard testimony that suggested that this market has increased over time.

And, again, if we're going to go back and try to figure out what would have happened, where would

these -- what would have happened in terms of the but-for world, how many additional sales would Remicade have made, we have to adjust for the fact that one of the reasons the market grew was because Humira was on the market.

Q. Now, we heard testimony yesterday about the fact that the market did grow over time, and I just want to turn to DX194, which is a slide that Mr. Beck showed to Dr. Gering.

MS. WIGMORE: And if we could turn to the page that Dr. Gering was shown during his cross-examination.

Q. (By Ms. Wigmore) Now, this is a slide that shows market growth in 2005.

Do you see that?

A. Yes.

Q. And do you recall that the market growth was attributed, in part at least, to the entrance of Humira on the market?

A. Yes.

Q. Now, what impact should that have had on the lost profits analysis?

A. Again, if Dr. Gering is going to try to construct what the world would have looked like without licensed Humira, then he should also take into account

the fact that the market grew and benefited from Humira being in the market and adjusted it downward. And he didn't do that.

MS. WIGMORE: And if we can now turn to Page 16 of DX194.

Q. (By Ms. Wigmore) Could you just read the top line on that slide, please?

A. Biologic class penetration among RA patients increased in the first quarter of 2006 and reached a new all-time high, driven primarily by Humira.

Q. Now, what, if anything, did Dr. Gering do to account for that in his but-for world?

A. The calculation of damages I've seen, he didn't do anything.

Q. Now, we've heard testimony that Remicade's market share has gone down since Humira was launched. What is the relationship between market share and market growth?

A. Market share tells you what percentage of the market you have, but it doesn't tell you anything about how many sales you have.

So it's very conceivable that even though your share of the market may decline, if your sales go up, meaning the whole pie gets bigger, that's a pretty good thing.

Q. Now, what has happened to Remicade's sales since Humira was launched on the market?

A. They've gone up every year.

MS. WIGMORE: Let's turn to the next slide. This is DDX70.

Q. (By Ms. Wigmore) Can you explain what's shown on this slide?

A. This -- this slide shows that if you look at the time, roughly at the beginning of 2003 when Humira launched, Remicade's sales worldwide were about $1.7 billion.

After it launched, you can see every year it went up. That's why that line is positively sloped, and you can see in 2008, they were almost $2 billion higher than they were in back in 2003.

Q. Now, we've seen some slides about statements, indicating that Humira was taking market share from -- that Humira was taking market share from Remicade. Do you recall seeing those during the witness examinations you watched?

A. Yes.

Q. Were those documents relating to the gastroenterology market?

A. Most of them were.

Q. And how did you account for that in your lost

profits analysis?

A. Well, again, I have -- in my analysis, I have included and awarded lost profits in gastroenterology simply with respect to Crohn's.

Q. I just want to recap your overall opinions concerning lost profits.

Based on your analysis of the but-for world, considering all these differences we've been through, what, if any, areas do you believe -- in which of these areas do you believe lost profits would be appropriate, if the '775 patent is valid and infringed?

A. For Crohn's disease and from the period up to April of 2008.

Q. And aside from your opinion as to the indications in which lost profits should be available, do you have any other disagreements with Dr. Gering concerning lost profits?

A. Yes. To calculate lost profits, you have to take how many sales a company makes or how many sales of products that they make.

You have to determine, again -- if we're trying to determine lost profits on sales that weren't made, but would have been made in this but-for world, you have to figure out, all right, if they had sold an additional dollar of the product, how much of that

additional dollar would have been profit.

So you have to take out what's called incremental expenses or marginal -- you've heard the term marginal cost or incremental expenses.

And Dr. Gering and I disagree on how you calculate what that incremental profit rate would be or how you would subtract out those incremental expenses for each additional dollar of sales.

Q. Just to back up for a minute, Dr. Gering showed us how he calculated lost profits.

Do you recall that?

A. Yes.

Q. He started with the sales that were subject to lost profits, correct?

A. Yes.

Q. And then he multiplied that by an incremental profit margin.

A. Yes.

Q. To come up with a lost profits number.

A. Right.

Q. Now, the disagreement you have with him that you were just describing relates to that margin that you multiple by to reach the dollar amount --

A. Yes.

Q. -- is that right?

And you indicated that you don't think he's properly accounted for costs related to the product; is that right?

A. Yes.

Q. How has he failed to do that appropriately?

A. I looked at the actual data from Centocor with respect to their sales and their expenses, and then I let the data tell me how much, using some statistical methods, how much additional expenses would be based on additional sales.

My understanding of what Dr. Gering did is he actually talked to people at the company, and they kind of eyeballed and told him they thought this expense would vary, this expense would vary, as opposed to looking at the data themselves and let the data tell you what would happen.

Q. So if you do it in the more precise way that you've described, what impact does that have on the lost profits analysis?

A. The incremental expense number would be 5 percent higher, meaning the incremental profit numbers that he calculated would be 5 percent lower.

Q. Now, he gave us a lost profits number of roughly $1 billion.

What is 5 percent of that amount?

A. I think it's 50 million. I didn't calculate that, but I think that's right.

Q. So there's a significant impact of this error?

A. Yes.

Q. I want to turn now to your opinions concerning a reasonable royalty.

Now, if you can just explain for us when a reasonable royalty would be available as opposed to lost profits.

A. If you find that the product is infringed, then -- and you don't worry about lost profits, then on all sales that are made of the infringed product, you get a reasonable royalty.

Q. So if lost profits are not available based on the reasons you've described, then you would award a reasonable royalty?

A. Yes.

Q. Now, what if lost profits are awarded on certain indications or sales?

A. Well, in our example, I believe that lost profits are appropriate for Crohn's disease, but all the other sales that were made, Centocor -- I'm sorry -- Abbott would still pay a reasonable royalty on those.

The key thing is you want to make sure that you are not double counting. You either get a

reasonable royalty or you get a lost profit, but you don't get both.

Q. Now, did you hear Dr. Gering's testimony regarding the royalty rate he believes is appropriate?

A. Yes.

Q. What is that rate?

A. 15 percent.

Q. Do you agree with Dr. Gering's testimony that a 15 percent royalty rate is appropriate?

A. I do not agree with that.

Q. Have you done your own reasonable royalty analysis for purposes of this case?

A. Yes, I have.

Q. And what method did you use to determine a reasonable royalty?

A. I went through -- you heard it described.

It's called the Georgia-Pacific factors -- Georgia-Pacific analysis.

It's nothing more than looking at economic factors that you would expect would help you determine the price of a particular good. Here, the price is to use someone else's intellectual property.

Q. And let's turn briefly to DDX71. Are these the 15 specific Georgia-Pacific factors?

A. Yes.

Q. And, again, we won't belabor them by going through them each in detail, but could you tell us whether or not you applied each of these factors in your analysis?

A. I looked at every one of them.

Q. And when you did that, were there any particular factors where you and Dr. Gering differed most significantly in terms of your analysis?

A. Yes.

Q. And what were those?

A. Those would be Factor 2, which would be the rates that Abbott pays in other licenses; and then in Factor 15, the hypothetical negotiation. Those are the major areas of disagreement between us.

Q. And just backing up, the Georgia-Pacific analysis, as Dr. Gering told us, assumes there is this hypothetical negotiation. What is that?

A. Once again, just like we have an imaginary but-for world, we also have to pretend that if these parties were locked in a room and they were forced to stay in that room until they reached an agreement, and using all the economic information that they had at the time, what would have been a royalty that they would have reached where both parties would have found it fair and reasonable.

That's what the hypothetical negotiation is intended to do.

Q. And on what date did the hypothetical negotiation occur for purposes of the reasonable royalty analysis?

A. Right around July 4th of 2006.

Q. And is that the date that the '775 patent issued?

A. Yes.

Q. Do you and Dr. Gering agree on that date?

A. We do agree on that date.

Q. Let's turn briefly to your analysis of Factor 2. Explain for us what Factor 2 covers.

A. Factor 2 covers -- one of the things, if you were locked in this room together, that you would look at, if I was -- if you were Centocor, and I was Abbott, I would know what actual rates I had paid to others to use on -- on this same product or in similar technology. So the rates that Abbott paid on other licenses, what I would be focusing on is what I'm paying others to use this, if that's -- if that's the case. If it's not that case, then we go to Plan B.

But in this particular lawsuit, Plan A is -- we can do that, because we have a number of licenses where Abbott has actually taken licenses on the same

product, Humira.

Q. And did you consider those agreements -- those agreements between Abbott and other parties concerning Humira?

A. Yes.

Q. How many of those licenses did you rely on in your analysis?

A. I looked at four different licenses.

Q. And what is the range of royalty rates in this group of agreements?

A. It's less than 1 percent, .35, which is a third of 1 percent, up to about 4-1/2 percent.

Q. So the lowest is .35 percent, and the highest is 4-1/2 percent?

A. Yes.

Q. How does that compare to Dr. Gering's 15-percent royalty rate?

A. Well, they're, obviously, much lower than Dr. Gering's 15 percent.

Q. Now, why did you focus on those four agreements in particular?

A. Because, again, those are -- those are agreements that cover the same product. Abbott is already paying someone else, different parties, royalties on this very product. And to me, nothing can

be more relevant than the actual product itself in this particular case.

Q. Now, of the four agreements relating to Humira, do you consider any one of them particularly relevant?

A. Yes.

Q. And what was that?

A. That's the agreement between the same parties: Centocor and Abbott. They already have a license for the same product, Humira.

MS. WIGMORE: Let's turn to DDX221, which is already in evidence.

Q. (By Ms. Wigmore) Is this that agreement?

A. Yes.

Q. And what is the date of this agreement?

A. December 23rd, 2002.

Q. And you mentioned the parties are Centocor and Abbott; is that right?

A. Yes.

Q. When did this agreement take place in relation to the launch of Humira on the market in the U.S.?

A. Very, very close to the time that Humira actually launched. It was right after it.

Q. Now, you talked earlier about licensed Humira and an arbitration. Do you have an understanding as to

how this agreement relates to the licensed Humira we've been discussing?

A. This license covers -- this is the license that essentially accounts for the license -- what's called the licenseD Humira, the Humira taken with Methotrexate.

Q. And what is the scope of this license?

A. The scope of it?

Q. It covers like licensed Humira, which is Humira with Methotrexate?

A. With Methotrexate.

Q. Okay. And was there another agreement that was entered into at the same time? We heard some testimony about that yesterday.

A. Yes.

Q. Before we move to that agreement, what is the royalty rate specified in this agreement between Abbott and Centocor concerning licensed Humira?

A. I think that there's -- I don't think there's disagreement between us. The actual royalty rate that was paid is 2 percent.

It's a little -- it's higher in the agreement, but 2 percent is the actual rate, because what this agreement accounts for is the fact that, as we already said, Humira is paying royalties to other parties. And

since they were paying to other parties, they offset it or lowered this one, so it's 2 percent.

Q. So they started with a 4 percent rate, but offset other royalty payments by 2 percent to arrive at a 2 percent effective rate --

A. Yes.

Q. -- is that right?

Now, we were talking about another agreement that was entered at the same time.

MS. WIGMORE: And if we could turn to DX220, which is preadmitted.

Q. (By Ms. Wigmore) Is this that other agreement?

A. Yes.

Q. And this is a license from Abbott to Centocor; is that right?

A. Yes.

Q. And is there a particular -- if you look at the Section B on that first page, do you see the reference there to CNTO-148?

A. Yes.

Q. What is CNTO-148?

A. That is the product that you've heard referred to as golimumab and also finally in the market as Simponi or Simponi (pronouncing).

Q. So this is an agreement that applies to what

became Simponi?

A. Yes.

Q. What is the -- were you here yesterday when Dr. Gering talked about the value that would have been assigned to this agreement by Centocor?

A. Yes.

Q. And what -- remind us what he said about that.

A. There's a number of different documents kind of flying around that suggests that the various parties put a great deal of value on it. There's numbers in the billions. There's other numbers that suggest a smaller amount. But at the end of the day, the actual agreement says 2 percent.

MS. WIGMORE: Let's turn to Section 2.01 of the agreement. If we could highlight that.

Q. (By Ms. Wigmore) Is this the part of the agreement that -- where the royalty terms are described?

A. Yes.

MS. WIGMORE: And if you turn toward the bottom of that paragraph and if we could highlight the last couple of sentences.

Q. (By Ms. Wigmore) Can you just explain for us what royalty rate is established in this agreement?

A. The licensee's license under this agreement will be a royalty license at a rate of 2 percent of the

licensee's net rate.

Q. Now, are there situations in which there's no royalty?

A. Yes. If there happened to be sales that are covered by the other license that we talked about earlier, going the other way, then there would no -- there would be no royalty.

But if it's not covered in a particular country, then there would be a 2 percent royalty rate going from -- in this case, from Centocor to Abbott, instead of from Abbott to Centocor.

Q. And how did the 2 percent rate that's set forth both in the Centocor-to-Abbott agreement and the Abbott-to-Centocor agreement impact your reasonable royalty analysis?

A. Well, it's very important, because it's also consistent with both of these parties licensing with other parties.

So if we look at that 2 percent -- those 2 percent rates, which, again, is between these two actual parties over this actual product, it's very consistent with what Abbott did with other licensees over Humira, and it's also consistent with what Centocor did with Remicade.

Q. Now, we heard testimony yesterday from

Dr. Gering about the agreements he focused on in his reasonable royalty analysis.

Do you agree that those agreements were appropriate to focus on for that purpose?

A. I do not.

Q. Why not?

A. Well, as an example, he puts a lot of focus on this agreement you heard referred to as the Cordis agreement. The Cordis agreement has a very, very high rate of 26 percent. The Cordis agreement also covers heart stents.

So if you're trying to make a decision, which one do you think you should be looking at or the parties, when they're locked in this room, are going to rely on, would you rely on one that talks about heart stents, or would you talk about one with respect to the actual products that are the same -- very same products that the parties are talking about when they're locked in this room in 2006?

Q. Now, the Cordis agreement you mentioned is the one that had the three rates, but the highest was 26 percent?

A. Yeah. Goes from 3 to 15 to 26.

Q. Aside from that 26 percent, did any of the other agreements that Dr. Gering focused on have

anything approaching the 15 percent rate he selected?

A. No. They were all less than 10. I think they were 10 or -- there may have been one 12, but they were all less -- most of them were significantly less than --

Q. Now --

A. -- 15.

Q. I'm sorry.

Let's turn now to your analysis of Factor 15 of the Georgia-Pacific analysis.

MS. WIGMORE: If we could just go back briefly to the factors.

Q. (By Ms. Wigmore) Factor 15 is the hypothetical negotiation, generally. Could you describe what's involved in the analysis of Factor 15?

A. Factor 15 is where you take into account all of the information that you think is important in all these other factors, and you put it all together, and you try to figure out, when they would have unlocked that door, what would they have walked out with? What would be the rate they would have agreed on that they both considered reasonable?

MS. WIGMORE: If we could turn, please, to DDX72.

Q. (By Ms. Wigmore) Does this describe the way you approached your analysis of Factor 15?

A. Yes.

Q. And could you explain for us, please, what factors impacted your analysis of that factor.

A. I've already talked with you about why I think an actual license between these same parties would be very informative of what -- in 2002, they actually did this.

And I think that's informative of what they would have done when they got locked in that room in 2006. The royalty range that Humira is actually paying, as we already discussed, is less than 1 percent to 4-1/2.

In addition, I also mentioned to you something -- you heard -- I think you heard someone else discuss it as well, the idea of a royalty stack.

The royalty stack takes into account the fact that in this particular case, you know that Humira -- or Abbott is already paying royalties to a number of other parties.

In fact, there are six other parties that have intellectual property that Abbott has licensed on its product, Humira. And if you add those all up together, those other six parties are charging Abbott a total price of 16 to 17 percent as a royalty rate.

Q. And how does that bear on the reasonable

royalty analysis?

A. Well, it's very important, because if they're paying six other parties a total of 16 to 17 percent, how reasonable would it be to expect that they would pay another party 15 percent, which is almost as high as they're paying all the other six parties together? It just doesn't make sense to me as an economist.

Q. And did you also look at the royalty stack on Remicade?

A. I did.

Q. And how did that bear on your analysis?

A. Again, Remicade -- Centocor is also paying royalties. And remember, they're locked in that room, too. They know that they're paying their licensing partners between 11 and 14 percent. Five different parties, they're paying between 11 and 14 percent. So when you look at both of those things, obviously, this rate that's been suggested of 15 percent is higher than the total royalty stack that Centocor is paying on Remicade, as well as almost as high as what Humira is paying on -- sorry -- what Abbott is paying on Humira, and it doesn't make sense.

Q. Now let's turn to the last factor you mentioned in here, research and development cost. Can you describe, first of all, what those are and then how

they bear on your analysis.

A. One of the suggestions that was made by Dr. Gering is that he looked at Humira's profit margin, and he said they make a big profit margin of 47 percent, and they could take 15 percent of that.

And you saw that dollar bill thing he had, and --

Q. And we can actually pull that up, if I could just interrupt. We can show you that slide that we saw from Dr. Gering yesterday.

A. Okay.

Q. Did you agree with this allocation?

A. Absolutely not.

Q. Why not?

A. Because what he's failing to take into account is that 47 percent -- you've also heard -- you heard, I think, Mr. Scodari talk about -- and others talk about how risky these drugs are. It's very -- and the scientists talked -- all the scientists have talked about that all of these drugs, they can spend 400 to $600 million on a drug, and it fails.

That's a lot of money. So how can they do that? How can they afford to pay even, you know, 400, $600 million and have it fail?

Well, the reason you can do that is because,

on products that do well, you take the profits you make on these products, and you're able to fund the other research to bring other drugs to help other people and other -- you know, other diseases.

So it's important to understand that those profits in part are going to be used towards all these drugs that fail.

Q. Now, did this breakdown that Dr. Gering provided, his suggestion that it will be $32 of profit on every hundred dollars of sales that would be impacted by his damages analysis, did that analysis take into account research and development costs for Humira?

A. No. Research -- you heard -- I think you heard one of the scientists talk about the fact that his estimate was it was over a billion dollars that had been used. I've seen estimates as high as $2 billion on what has gone into the research and development of Humira that you also heard has helped so many patients.

Q. If you take into account those R&D costs, how would that impact this percentage of profit that would be impacted by the damages award Dr. Gering is proposing?

A. Well, the return that they would get would be much lower, and their ability to compete in the industry would be much lower.

Q. And let's talk about that a little bit more. What impact would it have on Abbott to require a significant portion of their profitability to be spent on -- on a damage award?

A. Well, again, it would affect their ability to invest in other drugs. It would cause competition in the markets to change and decline. It would cause the number of new drugs that they were able to go -- to start developing to decline.

Q. And is that relevant to the --

A. So it could affect competition, and it could affect innovation.

Q. Is that relevant in a reasonable royalty analysis?

A. Yes.

MS. WIGMORE: Now, let's go back to the previous slide, DX72.

Q. (By Ms. Wigmore) Based on your analysis of these factors, what did you conclude about a reasonable royalty should the '775 patent be found valid and infringed?

A. The 2.25 percent would be a reasonable royalty.

Q. And is that for the United States sales?

A. Yes.

Q. You also mentioned you have a different rate for sales outside the United States. What rate is that?

A. 1.25 percent.

Q. Can you explain for us why it is that you have two different rates, one for U.S. sales and one for sales outside the U.S.?

A. There's a little -- there's a little nuance, a little -- it's an interesting fact that in order to get a royalty, you have to make, use, and sell the stuff in the United States, if you're going to get a royalty payment in the United --

THE COURT: It's not make and; it's make or use.

THE WITNESS: I apologize, Your Honor.

THE COURT: Okay. You're starting to get over in the area where I tell them, okay? That's the law.

THE WITNESS: I'm sorry, Your Honor.

THE COURT: It's make or use.

THE WITNESS: I'm sorry, Your Honor.

THE COURT: Thank you.

A. So my understanding is, if it is made outside the United States and -- and whatever His Honor just said, then you don't pay a royalty in the U.S., is my understanding of that.

So one way in a negotiation is that you could suggest that you make them outside the U.S., and they would have the option to do that. And that's why I suggested the lower rate.

Q. (By Ms. Wigmore) So just to clarify some assumptions here, there are sales of Humira, as you understand, that are made outside the U.S., the sales.

A. Yes.

Q. And right now those sales are actually -- the product's made in the U.S.; is that right?

A. Right.

Q. And what did you -- what did you analyze in terms of manufacturing options for those sales as part of your reasonable royalty analysis?

A. They could have been made outside the U.S.

Q. Okay. And did you consider the cost that would be involved in changing manufacturing as part of that assessment?

A. Yes.

Q. And what did you conclude?

A. That it would -- could be economically feasible to do so.

Q. And so that explains why the rate for outside the U.S. sales is lower than the rate for U.S. sales?

A. Yes.

Q. Now, did Dr. Gering factor in the possibility of overseas manufacturing for these international sales in his analysis?

A. Not that I'm aware of.

Q. And would that be something the parties would consider as part of the reasonable royalty negotiation?

A. Yes.

Q. Now, let's just summarize where we are. You understand that there's a dispute in this case as to when Centocor provided notice to Abbott of its alleged infringement of the '775 patent.

A. Yes.

Q. And do you understand it's Abbott's position that damages, if any, should run from April 16th of 2007, the date on which the complaint was filed?

A. Yes.

Q. Do you understand it's Centocor's position that damages, if any, should run from the date the patent was issued on July 4th of 2006?

A. Yes.

Q. Do you have any opinion as to which of those dates is appropriate?

A. I do not.

Q. And have you provided calculations based alternatively on either date?

A. Yes.

Q. Now --

MS. WIGMORE: If we could turn to the next slide.

Q. (By Ms. Wigmore) Based on the opinions you've described about what lost profits should be available and what royalty rates should apply -- be applied, what did you conclude would be the appropriate damages if the '775 patent is found to be valid and infringed?

A. Lost profits of $108,295,000. Reasonable royalties on those sales that are not covered by lost profits of 100,852,000 for a total of lost profit and reasonable royalty of $209,147,000.

Q. And with respect to those numbers, which of the two notice dates that we just discussed did you apply?

A. This one is the April 16, 2007.

Q. Now, if the jury were to conclude that no lost profits are recoverable, but instead, all damages should be in the form of a reasonable royalty, what would the total amount be, assuming the April 16th of 2007 starting date?

A. 104,385,000.

Q. Now, you mentioned that you had done alternative calculations assuming a July 4th, 2006

starting date?

A. Yes.

Q. If that date's adopted, how would that impact the amounts that we see here?

A. They would be higher.

Q. Now, I just want to clarify something. Now, you mentioned that these are your damages calculations. Do you have an opinion as to whether Abbott actually owes this amount?

A. No.

Q. If Humira does not infringe the '775 patent, what amount of damages would be appropriate?

A. Zero.

Q. And if Humira -- if the '775 patent is invalid, what amount of damages would be appropriate?

A. Zero.

Q. Thank you.

MS. WIGMORE: I have no further questions. I pass the witness.

THE COURT: Who's going to do this cross-exam?

MR. MASLOWSKI: Steven Maslowski for Centocor, Your Honor.

THE COURT: Well, I don't want to disappoint you, Counsel, but have a seat.

We're going to do this in the morning, Ladies and Gentlemen. I don't want to disappoint anybody, but I don't know how long it will take, but you've had a pretty full day of it.

Let me talk to you a little bit about our schedule before I release you for the day.

Based on my -- by this time tomorrow -- by this time tomorrow, we're going to be through with the evidence for sure, and hopefully, a little -- about the time of the afternoon break, I should be able to release you to come back.

And as you'll recall, as I told you, we're not going to work on this case on Friday due to other commitments.

So, hopefully, we'll finish up sometime between 3:00 and 5:00 tomorrow afternoon, and then you'll come back on Monday. And I'll finalize the charge before I leave tomorrow afternoon, and we'll have everything ready to go first thing Monday morning. So that's the plan, to, hopefully, get out of here at least an hour and a half early tomorrow afternoon, I think you can -- unless somebody -- I'm going to visit with the lawyers this afternoon and see if I can't convince them that 3:30 would be a good time to go home tomorrow.

And so you can keep that in mind, and I will see you in the morning. It's real important to keep an open mind. You still haven't heard all the evidence in the case. You're going to hear cross-examination of this witness, and then I believe we'll have some rebuttal testimony, and then we'll be through.

So we need to wait until we hear all the evidence before you start making up your mind. Do not discuss this case with anyone. Do not do any research. Do not talk to anyone about the case. Keep those instructions.

Have a nice evening, drive safely, and I'll see you in the morning at 8:30.

COURT SECURITY OFFICER: All rise.

(Jury out.)

THE COURT: You can step down.

Court is in recess. I'll see counsel up here for just a moment.

(Bench conference.)

THE COURT: Okay. Give me about 10 minutes, and I'll see y'all in chambers, and we'll visit about the Court's Charge.

MR. SAYLES: Yes.

THE COURT: And we'll get that done.

And Mr. -- how long -- how long is cross going to last on this witness? I guess we ought to have -- you got any estimates there?

MS. ELDERKIN: I'm sure no more than an hour. I would think probably less than that. An hour at the most.

THE COURT: Okay. Well, I'm trying to make heroes out of all of you, so...

MR. BECK: And how long for rebuttal are you talking about?

MS. ELDERKIN: I actually think we could be finished by lunch.

THE COURT: Yeah. That's what I'm hoping. That's really what I'm hoping. I'm trying to make heroes out of you. I may have some comments about you and Mr. Sayles individually.

I really feel bad, Mr. Gillam. I haven't said anything to this jury about you.

MR. GILLAM: Your Honor, with all the discussion about age, I'm just waiting for Mr. Williams and Mr. Beck to fall out, and then I'll be here in the wings to take care of them.

THE COURT: Okay. Who's going to take care of me? I mean, we're awful close in age.

All right. I'll see y'all in just a few

minutes. Give me about 10 minutes.

(Court adjourned.)

* * * * *

CERTIFICATION

I HEREBY CERTIFY that the foregoing is a true and correct transcript from the stenographic notes of the proceedings in the above-entitled matter to the best of my ability.

/s/_____ _____
SUSAN SIMMONS, CSR Date
Official Court Reporter
State of Texas No.: 267
Expiration Date: 12/31/10

/s/_____ _____
JUDITH WERLINGER, CSR Date
Deputy Official Court Reporter
State of Texas No.: 731
Expiration Date 12/31/10